

MATERIAL SAFETY DATA SHEET

Section 1 –Identification

Product Name: Foley Catheter, 3-way
 Product Size: Various
 Product Numbers COVERED: GMID3F16FR
 Manufacturer: Greystone Medical LLC
 Address: 7433 Pine Creek Trail Suite #B
 City: Waterford
 State: MI
 ZIP: 48327
 Country: US
 Phone Number: 248-919-8491

[MATERIAL A – C6-235 ELASTOMER]

Section 2 - Hazards Identification

Emergency Overview
 Appearance : Rubber-Crepe
 Colour : Colorless to pale yellow
 Odour : No data available
 Not a hazardous substance or mixture.

GHS Classification: Not a hazardous substance or mixture.
 GHS Label element: Not a hazardous substance or mixture.
 Physical and chemical hazards: Not classified based on available information.
 Health hazards: Not classified based on available information.
 Environmental hazards: Not classified based on available information.
 Other hazards which do not result in classification: None known

Section 3 - Composition/Information on Ingredients

Substance / Mixture: Mixture

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
Silicon dioxide	7631-86-9	>= 20 - < 30
Octamethylcyclotetrasiloxane	556-67-2	>= 0.1 - < 1

Section 4 - First Aid Measures

If inhaled	If inhaled, remove to fresh air. Get medical attention if symptoms occur.
In case of skin contact	Wash with water and soap as a precaution. Get medical attention if symptoms occur.
In case of eye contact	Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.
If swallowed	If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	None known.
Protection of first-aiders	No special precautions are necessary for first aid responders.
Notes to physician	Treat symptomatically and supportively.

Section 5 - Fire Fighting Measures

Suitable extinguishing media	Water spray, Alcohol-resistant foam, Carbon dioxide (CO ₂), Dry chemical
Unsuitable extinguishing media	None known.
Specific hazards during fire-fighting	Exposure to combustion products may be a hazard to health.
Hazardous combustion products	Carbon oxides, Silicon oxides, Formaldehyde
Specific extinguishing methods	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area
Special protective equipment	Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.

Section 6 – Accidental Release Measures

Personal precautions, protective equipment and emergency procedures	Follow safe handling advice and personal protective equipment recommendations.
Environmental precautions	Discharge into the environment must be avoided. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	Sweep up or vacuum up spillage and collect in suitable container for disposal. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements

Section 7 - Handling and Storage

HANDLING

Technical measures	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section
Local/Total ventilation	Use only with adequate ventilation.
Advice on safe handling	Handle in accordance with good industrial hygiene and safety practice. Take care to prevent spills, waste and minimize release to the environment.

STORAGE

Avoidance of contact	Oxidizing agents
Conditions for safe storage	Keep in properly labelled containers. Store in accordance with the particular national regulations.
Materials to avoid Materials to avoid	Do not store with the following product types: Strong oxidizing agents
Packaging material	Unsuitable material: None know

Section 8 - Exposure Controls/Personal Protection

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Silicon dioxide	7631-86-9	PC-TWA (Total dust)	5 mg/m ³	GBZ 2.1-2007
Octamethylcyclotetrasiloxane	556-67-2	TWA	10 ppm	DCC OEL

Engineering measures	Processing may form hazardous compounds (see section 10). Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations.
Personal protective equipment	
Respiratory protection	No personal respiratory protective equipment normally required
Eye/face protection	Wear the following personal protective equipment: safety glasses
Skin and body protection	Skin should be washed after contact.
Hand protection	
Remarks	Wash hands before breaks and at the end of workday.
Hygiene measure	Ensure that eye flushing systems and safety showers are located close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. These precautions are for room temperature handling. Use at elevated temperature or aerosol/spray applications may require added precautions.

Section 9 - Physical/Chemical Properties

Appearance	Rubber-Crepe
Colour	Colorless to pale yellow
Odour	No data available
Odour Threshold	No data available
pH	Not applicable
Melting point/freezing point	No data available
Initial boiling point and boiling range	Not applicable
Flash point	> 100 °C; Method: closed cup

Evaporation rate	Not applicable
Flammability (solid, gas)	Not classified as a flammability hazard
Upper explosion limit	No data available
Lower explosion limit	No data available
Vapour pressure	Not applicable
Relative vapour density	No data available
Relative density	1.11
Solubility(ies)	
Water solubility	No data available
Partition coefficient: noctanol/water	No data available
Auto-ignition temperature	No data available
Decomposition temperature	No data available
Viscosity	
Viscosity, dynamic	Not applicable
Explosive properties	Not explosive
Oxidizing properties	The substance or mixture is not classified as oxidizing.
Molecular weight	No data available
Section 10 - Stability and Reactivity Data	
Reactivity	Not classified as a reactivity hazard
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	Can react with strong oxidizing agents. When heated to temperatures above 150 °C (300 °F) in the presence of air, product can form formaldehyde vapours. Safe handling conditions may be maintained by keeping vapour concentrations within the occupational exposure limit for formaldehyde. Hazardous decomposition products will be formed at elevated temperatures.
Conditions to avoid	None known
Incompatible materials	Oxidizing agents
Hazardous decomposition products	
Thermal decomposition	Formaldehyde

Section 11 - Toxicological Information

Exposure routes

Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Components:

Silicon dioxide:

Acute oral toxicity

LD50 (Rat): > 3,300 mg/kg

Assessment: The substance or mixture has no acute oral toxicity

Remarks: Information taken from reference works and the literature.

Acute inhalation toxicity

LC50 (Rat): > 2.08 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Assessment: The substance or mixture has no acute inhalation toxicity

Remarks: Information taken from reference works and the literature.

Acute dermal toxicity

LD50 (Rabbit): > 5,000 mg/kg

Assessment: The substance or mixture has no acute dermal toxicity

Remarks: Information taken from reference works and the literature.

Octamethylcyclotetrasiloxane:

Acute oral toxicity

LD50 (Rat): > 4,800 mg/kg

Assessment: The substance or mixture has no acute oral toxicity

Remarks: Based on test data

Acute inhalation toxicity

LC50 (Rat): 2975 ppm

Exposure time: 4 h

Test atmosphere: vapour

Assessment: The substance or mixture has no acute inhalation toxicity

Remarks: Based on test data

Acute dermal toxicity

LD50 (Rabbit): > 2.5 ml/kg

Assessment: The substance or mixture has no acute dermal toxicity

Remarks: Based on test data

Skin corrosion/irritation

Not classified based on available information.

Components:

Silicon dioxide:

Result: No skin irritation

Remarks: Information taken from reference works and the literature.

Octamethylcyclotetrasioane:

Species: Rabbit

Result: No skin irritation

Remarks: Based on test data

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Silicon dioxide:

Result: No eye irritation

Remarks: Information taken from reference works and the literature.

Octamethylcyclotetrasioane:

Species: Rabbit

Result: No eye irritation

Remarks: Based on test data

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Components:

Silicon dioxide:

Assessment: Does not cause skin sensitisation.

Test Type: Skin: test type not specified

Species: Guinea pig

Remarks: No known sensitising effect.

Information taken from reference works and the literature.

Octamethylcyclotetrasioane:

Assessment: Does not cause skin sensitisation.

Test Type: Maximisation Test (GPMT)

Species: Guinea pig

Remarks: Based on test data

Germ cell mutagenicity
Not classified based on available information.

Product:

Genotoxicity in vitro Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Remarks: Based on test data

Components:

Silicon dioxide:

Genotoxicity in vitro Result: negative
Remarks: Information taken from reference works and the literature.

Genotoxicity in vivo Application Route: Ingestion
Result: negative
Remarks: Information taken from reference works and the literature.

Germ cell mutagenicity -Assessment Animal testing did not show any mutagenic effects.

Octamethylcyclotetrasiloxane

Genotoxicity in vitro Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Remarks: Based on test data

Test Type: Mutagenicity (in vitro mammalian cytogenetic test)
Result: negative
Remarks: Based on test data

Test Type: Chromosome aberration test in vitro
Result: negative
Remarks: Based on test data

Test Type: In vitro sister chromatid exchange assay in mammalian cells
Result: negative
Remarks: Based on test data

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: negative
Remarks: Based on test data

Genotoxicity in vivo Test Type: Mammalian erythrocyte micronucleus test (in vivo)

cytogenetic assay)
Species: Rat
Application Route: inhalation (vapour)
Result: negative
Remarks: Based on test data

Test Type: Rodent dominant lethal test (germ cell) (in vivo)
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on test data

Germ cell mutagenicity-assessment Animal testing did not show any mutagenic effects.

Carcinogenicity: Not classified based on available information.

Reproductive toxicity: Not classified based on available information.

COMPONENTS

Octamethylcyclotetrasiloxane

Effects on fertility

Test Type: Two-generation reproduction toxicity study
Species: Rat, male and female
Application Route: inhalation (vapour)
Symptoms: Effects on fertility
Remarks: Based on test data

Effects on foetal development

Test Type: Prenatal development toxicity study (teratogenicity)
Species: Rabbit
Application Route: inhalation (vapour)
Symptoms: No effects on foetal development
Remarks: Based on test data

Reproductive toxicity - Assessment

Some evidence of adverse effects on sexual function and fertility, based on animal experiments.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Components:

Octamethylcyclotetrasiloxane:

Exposure routes: Ingestion

Assessment: No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

Exposure routes: inhalation (vapour)

Assessment: No significant health effects observed in animals at concentrations of 1 mg/l/6h/d or

less.

Exposure routes: Skin contact

Assessment: No significant health effects observed in animals at concentrations of 200 mg/kg bw or less

Repeated dose toxicity

Components: Octamethylcyclotetrasiloxane:

Species: Rat

Application Route: Ingestion

Remarks: Based on test data

Species: Rat

Application Route: inhalation (vapour)

Remarks: Based on test data

Species: Rabbit

Application Route: Skin contact

Remarks: Based on test data

Aspiration toxicity : Not classified based on available information.

Further information

Octamethylcyclotetrasiloxane:

Remarks: Results from a 2 year repeated vapour inhalation exposure study to rats of octamethylcyclotetrasiloxane (D4) indicate effects (benign uterine adenomas) in the uterus of female animals. This finding occurred at the highest exposure dose (700 ppm) only. Studies to date have not demonstrated if these effects occur through pathways that are relevant to humans. Based on the available information on its potential to cause harm to human health, Health Canada, in a 2008 screening assessment, has concluded that octamethylcyclotetrasiloxane is not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health (<http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=2481B508—1>). Repeated exposure in rats to D4 resulted in protoporphyrin accumulation in the liver. Without knowledge of the specific mechanism leading to the protoporphyrin accumulation the relevance of this finding to humans is unknown.

Section 12 – Ecological Information

Ecotoxicity

Components:

Octamethylcyclotetrasiloxane:

Toxicity to fish

LC50 (Oncorhynchus mykiss (rainbow trout)): > 0.022 mg/l
Exposure time: 96 h
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates

EC50 (Daphnia sp.): > 0.015 mg/l
Exposure time: 48 h

	Remarks: No toxicity at the limit of solubility
Toxicity to algae	EC50: > 0.022 mg/l Exposure time: 96 h Remarks: No toxicity at the limit of solubility
	NOEC: 0.022 mg/l Exposure time: 96 h Remarks: No toxicity at the limit of solubility
Toxicity to fish (Chronic toxicity)	NOEC (Oncorhynchus mykiss (rainbow trout)): >= 0.0044 mg/l Remarks: No toxicity at the limit of solubility
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	NOEC (Daphnia magna (Water flea)): > 0.0079 mg/l Exposure time: 21 cl Remarks: No toxicity at the limit of solubility
Toxicity to bacteria	C50: > 10,000 mg/l Method: ISO 8192
Ecotoxicology Assessment Chronic aquatic toxicity	May cause long lasting harmful effects to aquatic life.
Persistence and degradability Components: Octamethylcyclotetrasiloxane: Biodegradability	Result: Not readily biodegradable. Biodegradation: 3.7 % Exposure time: 28 Cl Method: OECD Test Guideline 310
Stability in water	Degradation half life: 69.3 - 144 h (24.6 °C) pH: 7 Method: OECD Test Guideline 111
Bioaccumulative potential Components: Octamethylcyclotetrasiloxane: Partition coefficient: noctanol/water	log Pow: 6.48 (25.1 °C)
Mobility in soil	No data available
Other adverse effects Components: Octamethylcyclotetrasiloxane:	

Results of PBT and vPvB

Remarks: Octamethylcyclotetrasiloxane (D4) meets the current REACH Annex X ||| criteria for PBT and vPvB. In Canada, D4 has been assessed and deemed to meet the PiT criteria. However, D4 does not behave similarly to known PBT/vPvB substances. The weight of scientific evidence from field studies shows that D4 is not biomagnifying in aquatic and terrestrial food webs. D4 in air will degrade by reaction with naturally occurring hydroxyl radicals in the atmosphere. Any D4 in air that does not degrade by reaction with hydroxyl radicals is not expected to deposit from the air to water, to land, or to living organisms.

Section 13 - Disposal Considerations

Disposal methods

Waste from residues

Dispose of in accordance with local regulations.

Contaminated packaging

Dispose of as unused product.
 Empty containers should be taken to an approved waste handling site for recycling or disposal.

Section 14 – Transport Information

International Regulation

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

GB 6944/12268

Not regulated as a dangerous good

Section 15 – Regulatory Information

National regulatory information

Law on Prevention and Control of Environment Pollution by Solid Waste

Law on the Prevention and Control of Occupational Diseases

The components of this product are reported in the following inventories:

REACH

All ingredients (pre-)registered or exempt.

TSCA	All chemical substances in this material are included on or exempted from listing on the TSCA Inventory of Chemical Substances.
PICCS	All ingredients listed or exempt.
KECI	All ingredients listed, exempt or notified
ENCS/ISHL	All components are listed on ENCS/ISHL or exempted from inventory listing.
IECSC	All ingredients listed or exempt.
AICS	All ingredients listed or exempt.
DSL	All chemical substances in this product comply with the CEPA 1999 and NSNR and are on or exempt from listing on the Canadian Domestic Substances List (DSL).

Inventories

AICS (Australia), DSL (Canada), IECSC (China), REACH (European Union), ENCS (Japan), ISHL (Japan), KECI (Korea), NZIoC (New Zealand), PICCS (Philippines), TCSI (Taiwan), TSCA (USA)

Section 16: Other Information

Greystone Medical LLC. is a registered Medical Devices manufacturer as designated by the FDA.

Disclaimer: This product is exempt from Safety Data Sheet regulations as the product is for consumer use. (Provided with this information by the compiling agencies):

This information contained in this SDS is offered as a guide to the handling of this specific material. The information contained in this Safety Data Sheet (SDS) is offered as a guide to the use and handling of this material. It has been prepared in good faith by technically knowledgeable

Personnel and it believed to be correct as of the effective date listed. All safety aspects of all Greystone Medical's products are thoroughly evaluated prior to commercialization Greystone Medical shall not be held liable for any damages, losses or injuries of any nature which may result from the use of or reliance upon any information contained in this SDS. Each individual should make a determination as to the suitability of the information for his or her particular purpose(s). Greystone Medical, LLC and the United States of America in no manner whatsoever, expressly or implied, warrants this information to be accurate and disclaims all liability for its use. Any person utilizing this document should seek competent

professional advice to verify and assume responsibility for the suitability of this information to their particular situation.

[MATERIAL B – C6-265 ELASTOMER]

Section 2 - Hazards Identification

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification: Not a hazardous substance or mixture.

GHS Label element: Not a hazardous substance or mixture.

Other hazards which do not result in classification: None known

Section 3 - Composition/Information on Ingredients

Substance / Mixture: Mixture

Chemical Nature: Silicone Elastomer

Hazardous components

Chemical name	CAS-No.	Concentration (% w/w)
Octamethylcyclotetrasiloxane	556-67-2	>= 0.1 - < 1

Section 4 - First Aid Measures

General advice

In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical

If inhaled

If inhaled, remove to fresh air.
Get medical attention if symptoms occur.

In case of skin contact

Wash with water and soap as a precaution.
Get medical attention if symptoms occur.
Remove contaminated clothing and shoes.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact

Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

If swallowed

If swallowed, DO NOT induce vomiting.
 Get medical attention if symptoms occur.
 Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed

None known.

Protection of first-aiders

First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists.

Notes to physician

Treat symptomatically and supportively.

Section 5 - Fire Fighting Measures

Suitable extinguishing media

Water spray, Alcohol-resistant foam, Carbon dioxide (CO₂),
 Dry chemical

Unsuitable extinguishing media

None known.

Specific hazards during fire-fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion products

Carbon oxides, Silicon oxides, Formaldehyde

Specific extinguishing methods

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
 Use water spray to cool unopened containers.
 Remove undamaged containers from fire area if it is safe to do so.
 Evacuate area

Special protective equipment

Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.

Section 6 – Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Use personal protective equipment.
 Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions	Discharge into the environment must be avoided. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	Sweep up or vacuum up spillage and collect in suitable container for disposal. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements
 Section 7 - Handling and Storage	
HANDLING	
Technical measures	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section
Local/Total ventilation	Use only with adequate ventilation.
Advice on safe handling	Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. Handle in accordance with good industrial hygiene and safety practice. Take care to prevent spills, waste and minimize release to the environment.
 STORAGE	
Conditions for safe storage	Keep in properly labelled containers. Store in accordance with the particular national regulations.
Materials to avoid	Do not store with the following product types: Strong oxidizing agents
Materials to avoid	
Packaging material	Unsuitable material: None know

Section 8 - Exposure Controls/Personal Protection

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Octamethylcyclotetrasiloxane	556-67-2	TWA	10 ppm	US WEEL

Engineering measures Processing may form hazardous compounds (see section10).
Ensure adequate ventilation, especially in confined areas.
Minimize workplace exposure concentrations.

Personal protective equipment
Respiratory protection Use respiratory protection unless adequate local exhaust ventilation is provided or exposure assessment demonstrates that exposures are within recommended exposure guidelines.

Filter type Organic vapour type

Hand protection
Material Chemical-resistant gloves

Remarks Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday

Eye protection Wear the following personal protective equipment:
Safety glasses

Skin and body protection Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

Hygiene measures Ensure that eye flushing systems and safety showers are located close to the working place.
When using do not eat, drink or smoke.

Wash contaminated clothing before re-use.
 These precautions are for room temperature handling. Use at elevated temperature or aerosol/spray applications may require added precautions.

Section 9 - Physical/Chemical Properties

Appearance	Rubber-Crepe
Colour	Colorless to pale yellow
Odour	No data available
Odour Threshold	No data available
pH	Not applicable
Melting point/freezing point	No data available
Initial boiling point and boiling range	Not applicable
Flash point	Not applicable
Evaporation rate	Not applicable
Flammability (solid, gas)	Not classified as a flammability hazard
Self-ignition	The substance or mixture is not classified as pyrophoric. The substance or mixture is not classified as self heating.
Upper explosion limit	No data available
Lower explosion limit	No data available
Vapour pressure	Not applicable
Relative vapour density	No data available
Relative density	1.23
Solubility(ies)	
Water solubility	No data available
Partition coefficient: noctanol/water	No data available
Auto-ignition temperature	No data available
Decomposition temperature	No data available
Viscosity	
Viscosity, dynamic	Not applicable
Explosive properties	Not explosive
Oxidizing properties	The substance or mixture is not classified as oxidizing.
Molecular weight	No data available

Section 10 - Stability and Reactivity Data

Reactivity	Not classified as a reactivity hazard
Chemical stability	Stable under normal conditions.

Possibility of hazardous reactions	Can react with strong oxidizing agents. When heated to temperatures above 150 °C (300 °F) in the presence of air, product can form formaldehyde vapours. Safe handling conditions may be maintained by keeping vapour concentrations within the occupational exposure limit for formaldehyde. Hazardous decomposition products will be formed at elevated temperatures.
Conditions to avoid	None known
Incompatible materials	Oxidizing agents
Hazardous decomposition products Thermal decomposition	Formaldehyde

Section 11 - Toxicological Information

Exposure routes	Skin contact Ingestion Eye contact
Acute toxicity	Not classified based on available information.
Components: Silicon dioxide: Acute oral toxicity	LD50 (Rat): > 4,800 mg/kg Assessment: The substance or mixture has no acute oral toxicity Remarks: On basis of test data
Acute inhalation toxicity	LC50 (Rat): 2975 ppm Exposure time: 4 h Test atmosphere: vapour Assessment: The substance or mixture has no acute inhalation toxicity Remarks: On basis of test data.
Acute dermal toxicity	LD50 (Rabbit): > 2.5 ml/kg Assessment: The substance or mixture has no acute dermal toxicity Remarks: On basis of test data.

Octamethylcyclotetrasioane:

Acute oral toxicity

LD50 (Rat): > 4,800 mg/kg

Assessment: The substance or mixture has no acute oral toxicity

Remarks: Based on test data

Acute inhalation toxicity

LC50 (Rat): 2975 ppm

Exposure time: 4 h

Test atmosphere: vapour

Assessment: The substance or mixture has no acute inhalation toxicity

Remarks: Based on test data

Acute dermal toxicity

LD50 (Rabbit): > 2.5 ml/kg

Assessment: The substance or mixture has no acute dermal toxicity

Remarks: Based on test data

Skin corrosion/irritation: Not classified based on available information.

Components:

Octamethylcyclotetrasioane:

Species: Rabbit

Result: No skin irritation

Remarks: Based on test data

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Octamethylcyclotetrasioane:

Species: Rabbit

Result: No eye irritation

Remarks: Based on test data

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Components:

Information taken from reference works and the literature.

Octamethylcyclotetrasioane:

Assessment: Does not cause skin sensitisation.

Test Type: Maximisation Test
Species: Guinea pig
Result: negative
Remarks: On basis of test data.

Germ cell mutagenicity
Not classified based on available information.

Components:

Octamethylcyclotetrasiloxane
Genotoxicity in vitro

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Remarks: Based on test data

Test Type: Mutagenicity (in vitro mammalian cytogenetic test)
Result: negative
Remarks: Based on test data

Test Type: Chromosome aberration test in vitro
Result: negative
Remarks: Based on test data

Test Type: In vitro sister chromatid exchange assay in mam-
malian cells
Result: negative
Remarks: Based on test da

Test Type: DNA damage and repair, unscheduled DNA syn-
thesis in mammalian cells (in vitro)
Result: negative
Remarks: Based on test d

Genotoxicity in vivo

Test Type: Mammalian erythrocyte micronucleus test (in vivo
cytogenetic assay)
Species: Rat
Application Route: inhalation (vapour)
Result: negative
Remarks: Based on test data

Test Type: Rodent dominant lethal test (germ cell) (in vivo)
Species: Rat

Application Route: Ingestion
Result: negative
Remarks: Based on test data

Germ cell mutagenicity-assessment Animal testing did not show any mutagenic effects.

Carcinogenicity: Not classified based on available information.
Reproductive toxicity: Not classified based on available information.

COMPONENTS

Octamethylcyclotetrasiloxane
Effects on fertility

Test Type: Two-generation reproduction toxicity study
Species: Rat, male and female
Application Route: inhalation (vapour)
Symptoms: Effects on fertility
Remarks: Based on test data

Effects on foetal development

Test Type: Prenatal development toxicity study (teratogenicity)
Species: Rabbit
Application Route: inhalation (vapour)
Symptoms: No effects on foetal development
Remarks: Based on test data

Reproductive toxicity - Assessment

Some evidence of adverse effects on sexual function and fertility, based on animal experiments.

STOT - single exposure : Not classified based on available information.
STOT - repeated exposure : Not classified based on available information.

Components:

Octamethylcyclotetrasiloxane:

Exposure routes: Ingestion

Assessment: No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

Exposure routes: inhalation (vapour)

Assessment: No significant health effects observed in animals at concentrations of 1 mg/l/6h/d or less.

Exposure routes: Skin contact

Assessment: No significant health effects observed in animals at concentrations of 200 mg/kg bw or less

Repeated dose toxicity

Components: Octamethylcyclotetrasiloxane:

Species: Rat

Application Route: Ingestion

Remarks: Based on test data

Species: Rat

Application Route: inhalation (vapour)

Remarks: Based on test data

Species: Rabbit

Application Route: Skin contact

Remarks: Based on test data

Aspiration toxicity : Not classified based on available information.

Further information

Octamethylcyclotetrasiloxane:

Remarks: Results from a 2 year repeated vapour inhalation exposure study to rats of octamethylcyclotetrasiloxane (D4) indicate effects (benign uterine adenomas) in the uterus of female animals. This finding occurred at the highest exposure dose (700 ppm) only. Studies to date have not demonstrated if these effects occur through pathways that are relevant to humans. Repeated exposure in rats to D4 resulted in protoporphyrin accumulation in the liver. Without knowledge of the specific mechanism leading to the protoporphyrin accumulation the relevance of this finding to humans is unknown.

Section 12 – Ecological Information

Ecotoxicity

Components:

Octamethylcyclotetrasiloxane:

Toxicity to fish LC50 (Cyprinodon variegatus (sheepshead minnow)): > 0.0063 mg/l

Exposure time: 336 h

Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates EC50 (Mysidopsis bahia (opossum shrimp)): > 0.0091 mg/l

Exposure time: 96 h

Remarks: No toxicity at the limit of solubility

Toxicity to algae ErC50 (Pseudokirchneriella subcapitata (green algae)): > 0.022 mg/l

Exposure time: 72 h

Remarks: No toxicity at the limit of solubility

Toxicity to fish (Chronic toxicity) NOEC: >= 0.0044 mg/l
 Species: Oncorhynchus mykiss (rainbow trout)

	Remarks: On basis of test data. No toxicity at the limit of solubility
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	NOEC: \geq 0.0079 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Remarks: On basis of test data. No toxicity at the limit of solubility
Ecotoxicology Assessment Chronic aquatic toxicity	May cause long lasting harmful effects to aquatic life.
Persistence and degradability Components: Octamethylcyclotetrasiloxane: Biodegradability	Result: Not readily biodegradable. Biodegradation: 3.7 % Exposure time: 28 d Method: OECD Test Guideline 310
Stability in water	Degradation half life: 69.3 - 144 h (24.6 °C) pH: 7 Method: OECD Test Guideline 111
Bioaccumulative potential Components: Octamethylcyclotetrasiloxane: Partition coefficient: noctanol/water	log Pow: 6.48 (25.1 °C)
Mobility in soil	No data available
Other adverse effects Components: Octamethylcyclotetrasiloxane: Results of PBT and vPvB	Remarks: Octamethylcyclotetrasiloxane (D4) meets the current REACh Annex X criteria for PBT and vPvB. In Canada, D4 has been assessed and deemed to meet the PiT criteria. However, D4 does not behave similarly to known PBT/vPvB substances. The weight of scientific evidence from field studies shows that D4 is not biomagnifying in aquatic and terrestrial food webs. D4 in air will degrade by reaction with naturally occurring hydroxyl radicals in the atmosphere. Any D4 in air that does not degrade by reaction with hydroxyl radicals is not expected to deposit from the air to water, to land, or to living

organisms.

Section 13 - Disposal Considerations

Disposal methods

Waste from residues

Dispose of in accordance with local regulations.

Contaminated packaging

Dispose of as unused product.

Empty containers should be taken to an approved waste handling site for recycling or disposal.

Section 14 – Transport Information

International Regulation

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Section 15 – Regulatory Information

Safety, health and environmental regulations/legislation specific for the substance or mixture

The components of this product are reported in the following inventories:

REACH

All ingredients (pre-)registered or exempt.

TSCA

All chemical substances in this material are included on or exempted from listing on the TSCA Inventory of Chemical Substances.

PICCS

All ingredients listed or exempt.

KECI

All ingredients listed, exempt or notified

ENCS/ISHL

All components are listed on ENCS/ISHL or exempted from inventory listing.

IECSC

All ingredients listed or exempt.

AICS	All ingredients listed or exempt.
DSL	All chemical substances in this product comply with the CEPA 1999 and NSNR and are on or exempt from listing on the Canadian Domestic Substances List (DSL).

Inventories

AICS (Australia), DSL (Canada), IECSC (China), REACH (European Union), ENCS (Japan), ISHL (Japan), KECI (Korea), NZIoC (New Zealand), PICCS (Philippines), TCSI (Taiwan), TSCA (USA)

Section 16: Other Information

Greystone Medical LLC. is a registered Medical Devices manufacturer as designated by the FDA.

Disclaimer: This product is exempt from Safety Data Sheet regulations as the product is for consumer use. (Provided with this information by the compiling agencies):

This information contained in this SDS is offered as a guide to the handling of this specific material. The information contained in this Safety Data Sheet (SDS) is offered as a guide to the use and handling of this material. It has been prepared in good faith by technically knowledgeable Personnel and it believed to be correct as of the effective date listed. All safety aspects of all Greystone Medical's products are thoroughly evaluated prior to commercialization Greystone Medical shall not be held liable for any damages, losses or injuries of any nature which may result from the use of or reliance upon any information contained in this SDS. Each individual should make a determination as to the suitability of the information for his or her particular purpose(s). Greystone Medical, LLC and the United States of America in no manner whatsoever, expressly or implied, warrants this information to be accurate and disclaims all liability for its use. Any person utilizing this document should seek competent professional advice to verify and assume responsibility for the suitability of this information to their particular situ