



Factor II, Incorporated

The Art, Science and Technology of
Silicones and Prosthetics...

Safety Data Sheet

Product Code A-165

Revision Date: 10/14/2017

SECTION 1: IDENTIFICATION

PRODUCT IDENTIFIER

Product Name Elastomer

Product Code A-165

Intended Use(s) : For professional use only

CONTACT INFORMATION FOR SUPPLIER OF SAFETY DATA SHEET

Factor II, Incorporated
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EMERGENCY TELEPHONE NUMBERS

928- 368-7502

SECTION 2: HAZARD(S) IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200

Reproductive toxicity Category 2

GHS label elements

Hazard pictograms



Signal Word

Warning

Hazard Statements

H361f Suspected of damaging fertility.

Precautionary Statements

Prevention:

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.



Response	P308 + P313 IF exposed or concerned: Get medical advice/ attention.
Storage	P405 Store locked up.
Disposal	P501 Dispose of contents/ container to an approved waste disposal plant.
Other hazards	None known.

SECTION 3: HAZARDOUS INGREDIENTS

Substance / Mixture	Mixture
Chemical nature	Silicone elastomer

Hazardous ingredients

Chemical name	CAS-No.	Concentration (% w/w)
Dimethyl, Methyl Vinyl Siloxane, Hydroxy-term and Dimethyl Siloxane, Hydroxy-term reaction with Silica	Not Assigned	>= 34 - <= 50
Octamethylcyclotetrasiloxane	556-67-2	>= 0.31 - <= 0.43

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 advice.
If inhaled	If inhaled, remove to fresh air. Get medical attention.
In case of skin contact	In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. 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.



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Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed

Suspected of damaging fertility.

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 for fire-fighters

In the event of fire, wear self-contained breathing apparatus.

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.



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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

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, based on the results of the workplace exposure assessment
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage

Keep in properly labeled containers.
Store in accordance with the particular national regulations.

Materials to avoid

Do not store with the following product types:
Strong oxidizing agents

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Ingredients with workplace control parameters

Ingredients	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Dimethyl, Methyl Vinyl	Not Assigned	TWA (Dust)	20 Million	OSHA Z-3



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Siloxane, Hydroxy-term and Dimethyl Siloxane, Hydroxy-term reaction with Silica			particles per cubic foot (Silica)	
		TWA (Dust)	80 mg/m ³ / % SiO ₂ (Silica)	OSHA Z-3
		TWA	6 mg/m ³ (Silica)	NIOSH REL
Octamethylcyclotetrasiloxane	556-67-2	TWA	10 ppm	US WEEL

These substance(s) are inextricably bound in the product and therefore do not contribute to a dust inhalation hazard.

Dimethyl, Methyl Vinyl Siloxane, Hydroxy-term and Dimethyl Siloxane, Hydroxy-term reaction with Silica

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

General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection

Material

Chemical-resistant gloves

Remarks

Choose gloves to protect hands against chemicals depending on the concentration 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 afore mentioned 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 AND CHEMICAL PROPERTIES

Appearance	Rubber-Crepe
Color	No data available
Odor	No data available
Odor 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 / Upper flammability limit	No data available
Lower explosion limit / Lower flammability limit	No data available
Vapor pressure	Not applicable
Relative vapor density	No data available
Relative density	1.2
Solubility(ies)	
Water solubility	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition 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
Particle size	No data available



SECTION 10: STABILITY AND REACTIVITY

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 vapors. Safe handling conditions may be maintained by keeping vapor concentrations within the occupational exposure limit for formaldehyde. See OSHA formaldehyde standard, 29 CFR 1910.1048 Formaldehyde may cause cancer. It is also toxic by inhalation, skin absorption and ingestion, corrosive to skin and eyes, and may cause skin sensitization and respiratory irritation. 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

Information on likely routes of exposure	Skin contact Ingestion Eye contact
Acute toxicity	Not classified based on available information.
<u>Ingredients:</u>	
Octamethylcyclotetrasiloxane:	
Acute oral toxicity	LD50 (Rat): > 4,800 mg/kg <i>Assessment:</i> The substance or mixture has no acute oral toxicity <i>Remarks:</i> On basis of test data.
Acute inhalation toxicity	LC50 (Rat): 2975 ppm <i>Exposure time:</i> 4 h <i>Test atmosphere:</i> vapor <i>Assessment:</i> The substance or mixture has no acute inhalation toxicity <i>Remarks:</i> On basis of test data.



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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.

Skin corrosion/irritation

Not classified based on available information.

Ingredients:

Octamethylcyclotetrasiloxane:

Species: Rabbit

Result: No skin irritation

Remarks: On basis of test data.

Serious eye damage/eye irritation

Not classified based on available information.

Ingredients:

Octamethylcyclotetrasiloxane

Species: Rabbit

Result: No eye irritation

Remarks: On basis of test data.

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Ingredients:

Octamethylcyclotetrasiloxane

Assessment: Does not cause skin sensitization.

Test Type: Maximization Test

Species: Guinea pig

Result: negative

Remarks: On basis of test data.

Germ cell mutagenicity

Not classified based on available information.

Ingredients:

Octamethylcyclotetrasiloxane:

Genotoxicity in vitro

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Remarks: On basis of test data.

Test Type: Mutagenicity (in vitro mammalian cytogenetic test)

Result: negative

Remarks: On basis of test data.

Test Type: Chromosome aberration test in vitro

Result: negative

Remarks: On basis of test data.



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Test Type: In vitro sister chromatid exchange assay
in mam-malian cells

Result: negative

Remarks: On basis of test data.

Test Type: DNA damage and repair, unscheduled
DNA syn-thesis in mammalian cells (in vitro)

Result: negative

Remarks: On basis of test data.

Genotoxicity in vivo

Test Type: Mammalian erythrocyte micronucleus
test (in vivo cytogenetic assay)

Species: Rat

Application Route: inhalation (vapor)

Result: negative

Remarks: On basis of test data.

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

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: On basis of test data.

Germ cell mutagenicity - Assessment

Animal testing did not show any mutagenic effects.

Carcinogenicity

Not classified based on available information.

IARC

No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA

No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP

No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Suspected of damaging fertility.

Ingredients:

Octamethylcyclotetrasiloxane:

Effects on fertility

Test Type: Two-generation reproduction toxicity
study

Species: Rat, male and female

Application Route: inhalation (vapor)

Symptoms: Effects on fertility.

Remarks: On basis of test data.



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Effects on fetal development *Test Type:* Prenatal development toxicity study (teratogenicity)
Species: Rabbit
Application Route: inhalation (vapor)
Symptoms: No effects on fetal development.
Remarks: On basis of 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.

Ingredients:

Octamethylcyclotetrasiloxane

Routes of exposure: Ingestion

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

Routes of exposure: inhalation (vapor)

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

Routes of exposure: Skin contact

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

Repeated dose toxicity

Ingredients:

Octamethylcyclotetrasiloxane

Species: Rat

Application Route: Ingestion

Remarks: On basis of test data.

Species: Rat

Application Route: inhalation (vapor)

Remarks: On basis of test data.

Species: Rabbit

Application Route: Skin contact

Remarks: On basis of test data.

Aspiration toxicity

Not classified based on available information.



Further information

Ingredients:

Octamethylcyclotetrasiloxane:

Remarks: Results from a 2 year repeated vapor inhalation exposure study to rats of octamethyl-cyclotetrasiloxane (D4) indicate effects (benign uterine adenomas) in the uterus of female ani-mals. 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

Ingredients:

Dimethyl, Methyl Vinyl Siloxane, Hydroxy-term and Dimethyl Siloxane, Hydroxy-term reaction with Silica:

Ecotoxicology Assessment

Acute aquatic toxicity This product has no known ecotoxicological effects.

Chronic aquatic toxicity This product has no known ecotoxicological effects.

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 (Oncorhynchus mykiss (rainbow trout)): >= 0.0044 mg/l
Remarks: On basis of test data. No toxicity at the limit of solubility.



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Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

NOEC (Daphnia magna (Water flea)): ≥ 0.0079 mg/l

Exposure time: 21 d

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

Ingredients:

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

Ingredients:

Octamethylcyclotetrasiloxane

Bioaccumulation

Species: Pimephales promelas (fathead minnow)

Bioconcentration factor (BCF): 12,400

Partition coefficient: n-octanol/water

log Pow: 6.48 (25.1 °C)

Mobility in soil

No data available

Other adverse effects

Ingredients:

Octamethylcyclotetrasiloxane:

Results of PBT and vPvB assessment

Remarks: Octamethylcyclotetrasiloxane (D4) meets the current REACH Annex XIII 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

Resource Conservation and Recovery Act (RCRA)

This product has been evaluated for RCRA characteristics and does not meet the criteria of hazardous waste if discarded in its purchased form.

Waste from residues

Dispose of in accordance with local regulations.

Contaminated packaging

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

If not otherwise specified: Dispose of as unused product.

SECTION 14: TRANSPORT INFORMATION

International Regulations

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.

Domestic regulation

49 CFR Not regulated as a dangerous good

SECTION 15: REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards Reproductive toxicity



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SARA 313 This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know

Dimethyl Siloxane, Dimethylvinylsiloxo-terminated 68083-19-2

Dimethyl, Methyl Vinyl Siloxane, Hydroxy-term and Dimethyl Siloxane, Hydroxy-term reaction with Silica Not Assigned

Dimethyl, methylvinyl siloxane, dimethylvinyl-terminated 68083-18-1

California Prop. 65

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

California Permissible Exposure Limits for Chemical Contaminants

Dimethyl, Methyl Vinyl Siloxane, Hydroxy-term and Dimethyl Siloxane, Hydroxy-term reaction with Silica Not Assigned

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

- NZIoC** All ingredients listed or exempt.
- REACH** For purchases from Dow Corning EU legal entities, all ingredients are currently pre/registered or exempt under REACH. Please refer to section 1 for recommended uses. For purchases from non-EU Dow Corning legal entities with the intention to export into EEA please contact your DC representative/local office.
- IECSC** All ingredients listed or exempt.
- ENCS/ISHL** All components are listed on ENCS/ISHL or exempted from inventory listing.
- PICCS** All ingredients listed or exempt.
- DSL** This product contains one or more substances which are not on the Canadian Domestic Substances List (DSL). Import of this product into Canada has volume limitations. For volume limits please consult Dow Corning Regulatory Compliance.
- TSCA** All chemical substances in this product are either listed on the TSCA Inventory or are in compliance with a TSCA Inventory exemption.
- AICS** One or more ingredients are not listed or exempt.



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KECI All ingredients listed, exempt or notified.

TCSI All ingredients listed or exempt.

Additional regulatory information

Dimethyl, Methyl Vinyl Siloxane, Hydroxy-term and Dimethyl Siloxane, Hydroxy-term reaction with Silica

The United States Environmental Protection Agency (USEPA) has established a Significant New Use Rule (SNUR) for one of the components in this product. See 40 CFR § 721.10482

SECTION 16: OTHER INFORMATION

NFPA Hazard ID

Flammability

1 - Slight

Health

*** - Chronic hazard**

0 - Minimal

Physical Hazard

0 - Minimal

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