



Factor II, Incorporated

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

10/17/2018

Safety Data Sheet

A-103 Parts A & B

Date of Issue:

Revision Date: 06/28/2021

Factor II Inc. encourages the end user to read this document entirely and understand all sections of this SDS sheet prior to use. There is important information regarding this product. The end user is expected to follow all precautions outlined in this SDS.

SECTION 1: IDENTIFICATION

PRODUCT IDENTIFIER

Product Name : Medical Grade Elastomer

Product Code : A-103 Part A

Intended Use(s): For professional use only

CONTACT INFORMATION FOR SUPPLIER OF SAFETY DATA SHEET

Factor II, Incorporated
5642 White Mountain Ave
PO Box 1339
Lakeside AZ 85929
928-537-8387
www.factor2.com
sales@factor2.com

EMERGENCY TELEPHONE NUMBERS

928- 368-7502

SECTION 2: HAZARD(S) IDENTIFICATION

Hazard classification

This material is not hazardous under the criteria of the Federal OSHA Hazard Communication Standard 29CFR 1910.1200.

Other Hazards

No data available.

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

Chemical nature : Silicone compound.

This product is a mixture.

Contains no hazardous ingredients according to GHS.



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| Component | CASRN | Concentration |
|---|------------|---------------|
| Dimethyl Siloxane, dimethylvinyl-terminated | 68083-19-2 | 50-70 |
| Trimethylated silica | 68909-20-6 | 30-50 |
| Platinum Catalyst | N/A | <0.1 |

SECTION 4: FIRST-AID MEASURES

Description of First Aid Measures

General advice:

If potential for exposure exists refer to Section 8 for specific personal protective equipment.

Inhalation: Move person to fresh air; if effects occur, consult a physician.

Skin Contact: Wash off with plenty of water.

Eye Contact: Flush eyes thoroughly with water for several minutes. Remove contact lenses after the initial 1-2 minutes and continue flushing for several additional minutes. If effects occur, consult a physician, preferably an ophthalmologist.

Ingestion: No emergency medical treatment necessary.

Most important symptoms and effects, both acute and delayed: Aside from the information found under Description of First Aid Measures (above) and Indication of Immediate Medical Attention and Special Treatment Needed (below), any additional important symptoms and effects are described in Section 11: Toxicology Information.

Indication of any Immediate Medical Attention and Special Treatment Needed

Notes to Physician: No specific antidote. Treatment of exposure should be directed at the control of symptoms and the clinical condition of the patient.

SECTION 5: FIRE-FIGHTING MEASURES

Suitable extinguishing media: Water spray, Alcohol-resistant foam, Carbon Dioxide (CO₂), Dry Chemical.

Unsuitable extinguishing media: None known.

Special Hazards arising from the substance or mixture

Hazardous combustion products: Silicon Oxides, and Carbon Oxides.

Unusual Fire and Explosion Hazardous: Exposure to combustion products may be a hazard to health.



Advice for Fire Fighters

Fire Fighting Procedures: 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: 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. Prevent spreading over a wide area (e.g., by containment or oil barriers). 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: Soak up with inert absorbent material. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposals of this material, as well as those materials and item employed in the clean up of releases. You will need to determine which regulations are applicable. For large spills, provide dyking or other appropriate containment to keep the material from spreading. If dyked material can be pumped, Sections 13 and 15 of this SDS provide information regarding certain local or national requirements. See sections: 7, 8, 11, 12, and 13.

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling: Take care to prevent spills, waste and minimize release to the environment. Handle in accordance with good industrial hygiene and safety practice. Use only adequate ventilation. See Engineering Measures under EXPOSURE CONTROLS/ PERSONAL PROTECTION section.

Conditions for safe storage: Keep in properly labelled containers. Store in accordance with the particular national regulations.

Do not store with following product types: Strong oxidizing agents.
Unsuitable materials for containers: None known.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters



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If exposure limits exist, they are listed below. If no exposure limits are displayed, then no values are applicable.

Exposure controls

Engineering controls: Use local exhaust ventilation, or other engineering controls to maintain airborne levels below exposure limit requirements or guidelines. If there are no applicable exposure limit requirements or guidelines, general ventilation should be sufficient for most operations. Local exhaust ventilation may be necessary for some operations.

Individual protection measures

Eye/face protection: Use safety glasses (with side shields).

Skin protection

Hand protection: Use gloves chemically resistant to this material when prolonged or frequently repeated contact could occur. Examples of preferred glove barrier materials include: Butyl Rubber. Neoprene. Nitrile/butadiene rubber ("nitrile" or "NBR"). Ethyl vinyl alcohol laminate ("EVAL"). Polyvinyl alcohol ("PVA"). Polyvinyl chloride ("PVC" or "vinyl"). Viton. Examples of acceptable glove barrier materials include: Natural rubber ("latex"). **NOTICE:** The selection of a specific glove for a particular application and duration of use in a workplace should also take into account all relevant workplace factors such as, but not limited to: Other chemicals which may be handled, physical requirements (cut/ puncture protection, dexterity, thermal protection), potential body reactions to glove materials, as well as the instruction/ specifications provided by the glove supplier.

Other protection: Wear clean, body-covering clothing.

Respiratory protection: Respiratory protection should be worn when there is a potential to exceed the exposure limit requirements or guidelines. If there are no applicable exposure limit requirements or guidelines, wear respiratory protection when adverse effects such as respiratory irritation or discomfort have been experienced, or when indicated by your risk assessment process. For most conditions, no respiratory protection should be needed; however, if the material is heated or sprayed, use an approved air purifying respirator. The following are effective types of air-purifying respirators: Organic vapor cartridge with a particular pre-filter.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical State

Viscous liquid

Color

Translucent

Odor

None

Odor Threshold

No data available

pH

No data available

Melting point/ range

No data available

Freezing point

No data available

Boiling point (760mmHg)

> 70 °C (> 158 °F)

Flash point

Closed cup > 101 °C (> 214 °F)



| | |
|--|--|
| Evaporation Rate (Butyl Acetate = 1) | No data available |
| Flammability (solid, gas) | Not applicable |
| Lower explosion limit | No data available |
| Upper explosion limit | No data available |
| Vapor Pressure | No data available |
| Relative Vapor Density (air = 1) | No data available |
| Relative Density (water = 1) | 1.10 |
| Water Solubility | No data available |
| Partition coefficient: n-octanol/ water | No data available |
| Auto-ignition temperature | No data available |
| Decomposition temperature | No data available |
| Dynamic Viscosity | 115,000 mPa.s |
| Kinematic Viscosity | No data available |
| Explosive properties | Not explosive |
| Oxidizing properties | The substance or mixture is not classified as oxidizing. |
| Molecular weight | No data available |
| Particle size | Not applicable |

NOTE: The physical data presented above are typical values and should not be construed as a specification.

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 temperature 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 occupational exposure limit for formaldehyde.

Conditions to avoid: None known.

Incompatible materials: Oxidizing agents.

Hazardous decomposition products: Formaldehyde.

SECTION 11: TOXICOLOGICAL INFORMATION

Toxicological information appears in this section when such data is available.

Acute toxicity

Acute oral toxicity



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Very low toxicity if swallowed. Harmful effects not anticipated from swallowing small amounts.

As product: single dose oral LD50 has not been determined.

Based on information for component(s):

LD50, Rat, >5,000 mg/kg Estimated.

Acute dermal toxicity

Prolonged skin contact is unlikely to result in absorption of harmful amounts.

As product: The dermal LD50 has not been determined.

Based on information for component(s):

LD50, Rabbit, >2,000 mg/kg Estimated.

Acute inhalation toxicity

No adverse effects are anticipated from single exposure to vapor. Vapor from heated material may cause respiratory irritation.

As product: The LC50 has been determined.

Skin corrosion/ irritation

Brief contact is essentially nonirritating to skin.

Serious eye damage/eye irritation

May cause slight temporary eye irritation.

Corneal injury is unlikely.

Sensitization

Based on information for component(s):

For skin irritation: Did not cause allergic skin reactions when tested in humans.

For this family of materials: Did not cause allergic skin reactions when tested in guinea pigs.

For respiratory sensitization:

No relevant data found.

Specific Target Organ Systemic Toxicity (Single Exposure)

Evaluation of available data suggests that this material is not a STOT-SE toxicant.

Specific Target Organ Systemic Toxicity (Repeated Exposure)

No relevant data.

Carcinogenicity

No relevant data found.

Teratogenicity



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No relevant data found.

Reproductive toxicity

No relevant data found.

Mutagenicity

Contains a component(s) which were negative in in vitro genetic toxicity studies.

Aspiration Hazard

Based on physical properties, not likely to be an aspiration hazard.

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicological information appears in this section when such data is available.

Toxicity

No data available.

Persistence and degradability

No data available.

Bioaccumulative potential

No data available.

Mobility in soil

No data available.

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal methods: DO NOT DUMP INTO ANY SEWERS, ON THE GROUND, OR INTO ANY BODY OF WATER. All disposal practices must be in compliance with all Federal, State/Provincial and local laws and regulations. Regulations may vary in different locations. Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator. AS YOUR SUPPLIER, WE HAVE NO CONTROL OVER THE MANAGEMENT PRACTICES OR MANUFACTURING PROCESSES OF PARTIES HANDLING OR USING THIS MATERIAL. THE INFORMATION PRESENTED HERE PERTAINS ONLY TO THE PRODUCT AS SHIPPED IN ITS INTENDED CONDITION AS DESCRIBED IN MSDS SECTION: Composition Information. FOR UNUSED & UNCONTAMINATED PRODUCT, the preferred options include sending to a licensed, permitted: Incinerator or other thermal destruction device. For additional information, refer to: Handling & Storage Information, MSDS Section 7 Stability & Reactivity Information, MSDS Section 10 Regulatory Information, MSDS Section 15.

Treatment and disposal methods of used packaging: Empty containers should be



recycled or otherwise disposed of by an approved waste management facility. Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator. Do not re-use containers for any purpose.

SECTION 14: TRANSPORT INFORMATION

DOT

Not regulated for transport

Classification for SEA transport (IMO-IMDG):

Not regulated for transport.

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

Consult IMO regulations before transporting
in bulk.

Classification for AIR transport (IATA/ICAO):

Not regulated for transport.

This information is not intended to convey all specific regulatory or operational requirements/information relating to this product. Transportation classifications may vary by container volume and may be influenced by regional or country variations in regulations. Additional transportation system information can be obtained through an authorized sales or customer service representative. It is the responsibility of the transporting organization to follow applicable laws, regulations and rules relating to the transportation of the material.

SECTION 15: REGULATORY INFORMATION

Superfund Amendments and Reauthorization Act of 1986 Title III (Emergency Planning and Community Right-To-Know Act of 1986) Sections 311 and 312

No SARA Hazards

Superfund Amendments and Reauthorization Act of 1986 Title III (Emergency Planning and Community Right-To-Know Act of 1986) Section 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.

Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) Section 103

This material does not contain any components with CERCLA RQ.

Pennsylvania Right-To-Know

The following chemicals are listed because of additional requirements of Pennsylvania law:



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Components

Dimethyl Siloxane, Dimethylvinylsiloxyl-terminated
Hexamethyldisilazane reaction with Silica

CASRN

68083-19-2

68909-20-6

California Prop. 65

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

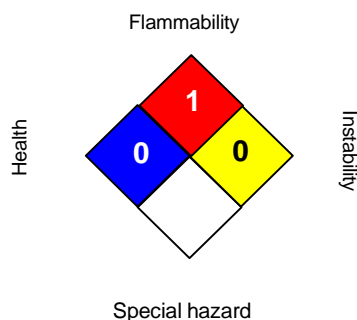
United States TSCA Inventory

All components of this product are in compliance with the inventory listing requirements of the U.S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory.

SECTION 16: OTHER INFORMATION

Hazard Rating System

NFPA



HMIS

| | |
|-----------------|----|
| HEALTH | 0* |
| FLAMMABILITY | 1 |
| PHYSICAL HAZARD | 0 |

0 = not significant, 1 = Slight, 2 = Moderate, 3 = High 4 = Extreme, * = Chronic effects (see Hazards Identification).

Full text of other abbreviations

AICS – Australian Inventory of Chemical Substances; ASTM – American Society for the Testing of Materials; bw – Body Weight; CERCLA – Comprehensive Environmental Response, Compensation, and Liability Act; CMR – Carcinogen, Mutagen or Reproductive Toxicant; DIN – Standard of the German Institute for Standardization; DOT – Department of Transportation; DSL – Domestic Substances List (Canada); ECx – Concentration associated with x% response; EHS – Extremely Hazardous Substance; ELx – Loading rate associated with x% response; EmS – Emergency Schedule; ENCS – Existing and New Chemical Substances (Japan); - ErCx – Concentration associated with x% growth rate response; ERG – Emergency Response Guide; GHS – Globally Harmonized System; GLP – Good Laboratory Practice; HMIS – Hazardous Materials Identification System; IARC – International Agency for Research on Cancer; IATA – International Air Transport Association; IBC – International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 – Half maximal inhibitory



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concentration; ICAO – International Civil Aviation Organization; IECSC – Inventory of Existing Chemical Substances in China; IMDG – International Maritime Dangerous Goods; IMO – International Maritime Organization; ISHL – Industrial Safety and Health Law (Japan); ISO – International Organization for Standardization; KECI – Korea Existing Chemicals Inventory; LC50 – Lethal Concentration to 50% of a test population; LD50 – Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL – International Convention for the Prevention of Pollution from Ships; MSHA – Mine Safety and Health Administration; n.o.s. – Not Otherwise Specified; NFPA – National Fire Protection Associations; NO(A)EC – No Observed (Adverse) Effect Concentration; NO(A)EL – No Observed (Adverse) Effect Level; NOELR – No Observable Effect Loading Rate; NTP – National Toxicology Program; NZIoC – New Zealand Inventory of Chemicals; OECD – Organization for Economic Co-operation and Development; OPPTS – Office of Chemical Safety and Pollution Prevention; PBT – Persistent, Bioaccumulative and Toxic substance; PICCS – Philippines Inventory of Chemicals and Chemical Substances; (Q) SAR – (Quantitative) Structure Activity Relationship; RCRA – Resource Conservation and Recovery Act; REACH – Regulation (EC) No 1907/2006 of the European Parliament and of the Council Concerning the Registration, Evaluation, Authorization and Restriction of Chemicals; RQ – Reportable Quantity; SADT – Self-Accelerating Decomposition Temperature; SARA – Superfund Amendments and Reauthorization Act; SDS – Safety Data Sheet; TCSI – Taiwan Chemical Substance Inventory; TSCA – Toxic Substance Control Act (United States); UN – United Nations; UNRTDG – United Nations Recommendations on the Transport of Dangerous Goods; vPvB – Very Persistent and Very Bioaccumulative.

Factor II, Inc. Disclaimer & Statement of Liability

This is to certify that the above designated material has been tested and did comply with the listed specifications (with listed exceptions) when supplied in original container. The material is subject to the conditions listed on the invoice. The above is a copy of information on file. The lot acceptance data are available for examination. This is a computer-generated document that is valid without a signature. The information above is supplied in good faith and, to the best of our knowledge, is based on available sources believed to be reliable and accurate. This document and any information provided herein are for your guidance only. The use by the requestor is beyond Factor II control; therefore, the responsibility for appropriate and safe use of the above information lies with the End user. Factor II shall not be responsible for any misuse and/or misapplication of the information in this document.

Factor II, Inc. urges each customer or recipient of this SDS to study it carefully to become aware of and understand the hazards associated with the product. The reader should consider consulting reference works or individuals who are experts in ventilation, toxicology and/or fire prevention as necessary or appropriate to the use and understanding of the data contained in this SDS. To promote safe handling each customer or recipient should 1) notify and furnish its employees, agents, contractors, customers and/or others whom it knows or believes will use this material of the information regarding hazards or safety, and 2) request its customers to notify their employees, customers, and other users of the product of this information.

SECTION 1: IDENTIFICATION

PRODUCT IDENTIFIER



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Product Name : Medical Grade Elastomer

Product Code : A-103 Part B

Intended Use(s) : For professional use only.

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5642 White Mountain Ave
PO Box 1339
Lakeside AZ 85929
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www.factor2.com
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EMERGENCY TELEPHONE NUMBERS

928- 368-7502

SECTION 2: HAZARD(S) IDENTIFICATION

Hazard classification

This material is not hazardous under the criteria of the federal OSHA Hazard Communication Standard 29CFR 1910.1200.

Label Elements

Precautionary statements

Prevention

Keep away from heat/ sparks/ open flames/ hot surfaces. No smoking.
Keep only in original container.

Storage

Store in well-ventilated area.

Other hazards

May generate flammable hydrogen gas. Avoid contact with water, alcohols, acids, basic, or oxidizing materials.

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS



Chemical nature : Silicone. This product is a mixture. Contains no hazardous ingredients according to GHS.

| Component | CASRN | Concentration |
|--------------------------|------------|---------------|
| Dimethyl Siloxane | 68083-19-2 | 70-90% |
| Dimethyl, Methylhydrogen | 68037-59-2 | 10-20% |

SECTION 4: FIRST-AID MEASURES

Description of first aid measures

General advice:

If potential exposure exists refer to Section 8 for specific personal protective equipment.

Inhalation: Move person to fresh air; if effects occur, consult a physician.

Skin contact: Wash off with plenty of water.

Eye contact: Flush eye thoroughly with water for several minutes. Remove contact lenses after the initial 1-2 minutes and continue flushing for several additional minutes. If effects occur, consult a physician, preferably an ophthalmologist.

Ingestion: No emergency medical treatment necessary.

Most important symptoms and effects, both acute and delayed: Aside from the information found under Description of first aid measures (above) and Indication of any medical attention and special treatment needed (below), any additional important symptoms and effects are described in Section 11: Toxicology Information.

Indication of any immediate medical attention and special treatment needed

Notes to physician: No specific antidote. Treatment of exposure should be directed at the control of symptoms and the clinical condition of the patient.

SECTION 5: FIRE-FIGHTING MEASURES

Suitable extinguishing media: Water spray, Alcohol-resistant foam, Carbon Dioxides (CO₂).

Unsuitable extinguishing media: Dry chemical.

Special hazards arising from the substance or mixture

Hazardous combustion products: Silicone oxides, Carbon oxides, Formaldehyde.

Unusual Fire and Explosion Hazards: Applying foam will release significant amounts of hydrogen gas that can be trapped under the foam blanket. Exposure to combustion products may be a hazard to health.



Advice for firefighters

Fire Fighting Procedures: Use extinguishing measures that are appropriate to the local circumstances and the surrounding environment. Use water spray to cool unopened containers. Collect contaminated fire extinguishing water spray separately. This must not be discharged into the drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations. Do not allow extinguishing medium to contact container contents. Most fire extinguishing media will cause hydrogen evolution, and once the fire is put out, may accumulate in poorly ventilated or confined areas and result in flash fire explosion if ignited. Remove undamaged containers from fire area if it is safe to do so. Evacuate the area.

Special protective equipment for firefighter: 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 it is safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and clean up: Soak up with inert absorbent material. Clean up remaining materials from spill with suitable absorbent. 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. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped. Materials in contact with water, moisture, acids or bases have the potential to generate hydrogen gas. Recovered material should be stored in a vented container. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements. Recovered material should be stored into a vented container. The vent must prevent the ingress of water as further reaction with spilled materials can take place which could lead to over pressurization of the container.
See Sections: 7, 8, 11, 12, and 13.

| |
|--|
| SECTION 7: HANDLING AND STORAGE |
|--|

Precautions for safe handling: Keep away from water. Protect from moisture. Take care to prevent spills, waste and minimize release to the environment. Handle in accordance with good industrial hygiene and safety practice.

Use only with adequate ventilation. See Engineering measures under EXPOSURE CONTROLS/ PERSONAL PROTECTION section.



Conditions for safe storage: Keep in properly labelled containers. Store in original container. Store in accordance with particular national regulations. Product may evolve minute quantities of flammable hydrogen gas which can accumulate. Adequately ventilate to maintain vapors well below flammability limits and exposure guidelines. Do not repackage. Clogged container vents may increase pressure build up. Store in closed container.

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

Unsuitable materials for containers: Do not store in or use containers except the original product package. Do not store in or use containers except the original product package.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

If exposure limits exist, they are listed below. If no exposure limits are displayed, then no values are applicable.

Exposure controls

Engineering controls: Use local exhaust ventilation, or other engineering controls to maintain airborne levels below exposure limit requirements or guidelines, general ventilation should be sufficient for most operations. Local exhaust ventilation may be necessary for some operations.

Individual protection measures

Eye/ face protection: Use safety glasses (with side shades).

Skin protection

Hand protection: Use gloves chemically resistant to this material when prolonged or frequently repeated contact could occur. Examples of preferred glove barrier materials include: Butyl Rubber. Neoprene. Nitrile/butadiene rubber ("nitrile" or "NBR"). Ethyl vinyl alcohol laminate ("EVAL"). Polyvinyl alcohol ("PVA"). Polyvinyl chloride ("PVC" or "vinyl"). Viton. Examples of acceptable glove barrier materials include: Natural rubber ("latex"). **NOTICE:** The selection of a specific glove for a particular application and duration of use in a workplace should also take into account all relevant workplace factors such as, but not limited to: Other chemicals which may be handled, physical requirements (cut/ puncture protection, dexterity, thermal protection), potential body reactions to glove materials, as well as the instruction/ specifications provided by the glove supplier.

Other protection: When prolonged or frequently repeated contact could occur, use protective clothing chemically resistant to this material. Selection of specific items such as face shield, boots, apron, or full body suit will depend on the task.

Respiratory protection: Respiratory protection should be worn when there is a potential to exceed the exposure limit requirements or guidelines. If there are no applicable exposure limit requirements or guidelines, wear respiratory protection when adverse effects such as respiratory irritation or discomfort have been experienced, or when indicated by your risk assessment process. For most conditions, no respiratory protection should be needed; however, if the material is heated or sprayed, use an approved air purifying respirator. The



following are effective types of air-purifying respirators: Organic vapor cartridge with a particular pre-filter.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**Appearance****Physical State**

liquid

Color

No data available

Odor

No data available

Odor Threshold

No data available

pH

No data available

Melting Point/ range

No data available

Freezing Point

No data available

Boiling Point (760 mmHg)

> 35 °C

Flash Point**closed up** > 101.1 °C (> 214.0 °F)**Evaporation Rate (Butyl Acetate = 1)**

No data available

Flammability (solid, gas)

Not applicable

Lower Explosion Limit

No data available

Upper Explosion Limit

No data available

Vapor Pressure

No data available

Relative Vapor Density (air = 1)

No data available

Relative Density (water = 1)

0.968

Water Solubility

No data available

Partition Coefficient: n- octanol/ water

No data available

Auto-ignition Temperature

No data available

Decomposition Temperature

No data available

Kinematic Viscosity500 mm²/s at 25 °C (77 °F)**Explosive Properties**

Not explosive

Oxidizing PropertiesThe substance or mixture is not classified
as oxidizing**Molecular Weight**

No data available

Particle Size

No data available

NOTE: The physical data presented above are typical values and should not be construed as a specification.

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



vapours. Safe handling conditions may be maintained by keeping vapour concentrations within the occupational exposure limit for formaldehyde.

Conditions to avoid: Exposure to moisture.

Incompatible materials: Oxidizing agents

Hazardous decomposition products: Formaldehyde.

SECTION 11: TOXICOLOGICAL INFORMATION

Toxicological information appears in this section when such data is available.

Acute Toxicity

Acute oral toxicity

Very low toxicity if swallowed. Harmful effects not anticipated from swallowing small amounts.

As product: Single dose oral LD50 has not been determined.

Based on information for component(s):

LD50, > 5,000 mg/kg Estimated.

Acute dermal toxicity

Prolonged skin contact is unlikely to result in absorption of harmful amounts.

As product: the dermal LD50 has not been determined.

Based on the information for component(s):

LD50, > 2,000 mg/kg Estimated.

Acute inhalation toxicity

At room temperature, exposure to vapor is minimal due to low volatility. Vapor from heated material or mist may cause respiratory irritation.

As product: the LD50 has not been determined.

Skin corrosion/irritation

Brief contact is essentially nonirritating to skin.

Serious eye damage/ eye irritation

May cause slight temporary eye irritation.

Corneal injury is unlikely.

Sensitization

Based on information for component(s):

For skin sensitization:



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For this family of materials:

Did not cause allergic reactions when tested in humans.

Did not cause allergic skin reactions when tested on guinea pigs.

For respiratory sensitization:

No relevant data found.

Specific Target Organ Systemic Toxicity (Single Exposure)

Evaluation of available data suggests that this material is not a STOT-SE toxicant.

Specific Target Organ Systemic Toxicity (Repeated Exposure)

No relevant data found.

Carcinogenicity

No relevant data found.

Teratogenicity

No relevant data found.

Reproductive Toxicity

No relevant data found.

Mutagenicity

In vitro genetic toxicity studies were negative.

Aspiration Hazard

Based on physical properties, not likely to be an aspiration hazard.

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicological information appears in this section when such data is available.

Toxicity

No data available

Persistence and Degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available



SECTION 13: DISPOSAL CONSIDERATIONS

Disposal Methods: DO NOT DUMP INTO ANY SEWERS, ON THE GROUND, OR INTO ANY BODY OF WATER. All disposal practices must be in compliance with all Federal, State/Provincial and local laws and regulations. Regulations may vary in different locations. Waste characterizations and compliance with applicable law are the responsibility solely of the waste generator. AS YOUR SUPPLIER, WE HAVE NO CONTROL OVER THE MANAGEMENT PRACTICES OR MANUFACTURING PROCESSES OF PARTIES HANDLING OR USING THIS MATERIAL. THE INFORMATION PRESENTED HERE PERTAINS ONLY TO THE PRODUCT AS SHIPPED IN ITS INTENDED CONDITION AS DESCRIBED IN MSDS SECTION: Composition Information. FOR UNUSED & UNCONTAMINATED PRODUCT, the preferred options must include sending a licensed, permitted: Incinerator or other thermal destruction device. For additional information refer to: Handling & Storage Information, MSDS Section 7. Stability & Reactivity, MSDS Section 10. Regulatory Information, MSDS Section 15.

Treatment and disposal methods of used packaging: Empty containers should be recycled or otherwise disposed of by an approved waste management facility. Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator. Do not re-use containers for any purpose.

SECTION 14: TRANSPORT INFORMATION

DOT

Not regulated for transport.

Classification for SEA transport (IMO-IMDG):

| | |
|-----------------------------------|---|
| Transport in bulk | Not regulated for transport. |
| according Annex I or II of | Consult IMO regulations before transporting ocean |
| MARPOL 73/78 and the | bulk |
| IBC or IGC Code | |

Classification for AIR transport (IATA/ICAO):

Not regulated for transport.

Further information:

VENTED PACKAGES ARE FORBIDDEN FOR AIR TRANSPORT.

This information is not intended to convey all specific regulatory or operational requirements/information relating to this product. Transportation classifications may vary by container volume and may be influenced by regional or country variations in regulations. Additional transportation system information can be obtained through an authorized sales or



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customer service representative. It is the responsibility of the transporting organization to follow applicable laws, regulations and rules relating to the transportation of the material.

SECTION 15: REGULATORY INFORMATION

Superfund Amendments and Reauthorization Act of 1986 Title III (Emergency Planning and Community Right-to-Know Act of 1986) Sections 311 and 312

No SARA Hazards.

Superfund Amendments and Reauthorization Act of 1986 Title III (Emergency Planning and Community Right-to-Know Act of 1986) Section 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.

Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) Section 103

This material does not contain any components with CERCLA RQ.

Pennsylvania Right-to-Know

The following chemicals are listed because of the additional requirements of Pennsylvania law:

| Components | CASRN |
|---|------------|
| Dimethyl Siloxane, Dimethylvinylsiloxo-terminated | 68083-19-2 |
| Dimethyl, Methylhydrogen Siloxane, Trimethylsiloxo-terminated | 68037-59-2 |

California Prop. 65

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

United States TSCA Inventory (TSCA)

All components of this product are in compliance with the inventory listing requirements of the U.S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory.

RoHS Directive (Restriction of the use of Certain Hazardous Substances)

To the best of our knowledge, the restricted substances prohibited in accordance with Directive 2011/65/EU and Directive 2015/863/EU are not normally expected to be present at or above the specified concentrations of 0.01% (by weight) for lead, mercury, hexavalent chromium, PBB, PBDE, (including decaBDE, PentaBDE, or OctaBDE), Phtalates (including DEHP, BBP, DBP and DIBP) and 0.01% (by weight) for cadmium.

REACH – Substances of Very High Concern (SVHC)

Octamethylcyclotetrasiloxane (CAS 556-67-2)
Decamethylcyclopentasiloxane (CAS 541-02-6)
Dodecamethylcyclohexasiloxane (CAS 540-97-6)



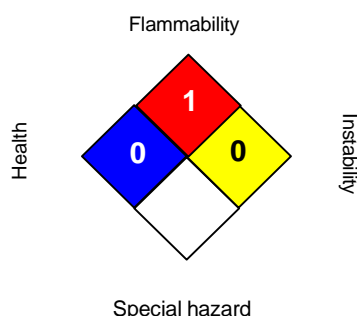
The above listed substances may be present in silicone-based products as unavoidable impurities of the basic silicone polymer synthesis steps currently used in the industry.

EU Medical Devices Regulation (MDR (EU) 2017/745)

Medical Grade Elastomer is not made with, nor does it generate carcinogenic, mutagenic or toxic to reproduction ('CMR'), of category 1A or 1B, or substances having endocrine-disrupting properties as defined in paragraph 10.4.1 of MDR (EU) 2017/745.

SECTION 16: OTHER INFORMATION

NFPA



HMIS

| | |
|------------------------|-----------|
| HEALTH | 0/ |
| FLAMMABILITY | 1 |
| PHYSICAL HAZARD | 1 |

0 = not significant, 1 = Slight, 2 = Moderate, 3 = High 4 = Extreme, * = Chronic effects (see Hazards Identification).

Full text of other abbreviations

AICS – Australian Inventory of Chemical Substances; ASTM – American Society for the Testing of Materials; bw – Body Weight; CERCLA – Comprehensive Environmental Response, Compensation, and Liability Act; CMR – Carcinogen, Mutagen or Reproductive Toxicant; DIN – Standard of the German Institute for Standardization; DOT – Department of Transportation; DSL – Domestic Substances List (Canada); ECx – Concentration associated with x% response; EHS – Extremely Hazardous Substance; ELx – Loading rate associated with x% response; EmS – Emergency Schedule; ENCS – Existing and New Chemical Substances (Japan); - ErCx – Concentration associated with x% growth rate response; ERG – Emergency Response Guide; GHS – Globally Harmonized System; GLP – Good Laboratory Practice; HMIS – Hazardous Materials Identification System; IARC – International Agency for Research on Cancer; IATA – International Air Transport Association; IBC – International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 – Half maximal inhibitory concentration; ICAO – International Civil Aviation Organization; IECSC – Inventory of Existing Chemical Substances in China; IMDG – International Maritime Dangerous Goods; IMO – International Maritime Organization; ISHL – Industrial Safety and Health Law (Japan); ISO – International Organization for Standardization; KECI – Korea Existing Chemicals Inventory; LC50 – Lethal Concentration to 50% of a test population; LD50 – Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL – International Convention for the Prevention of Pollution from Ships; MSHA – Mine Safety and Health Administration; n.o.s. – Not Otherwise



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Specified; NFPA – National Fire Protection Associations; NO(A)EC – No Observed (Adverse) Effect Concentration; NO(A)EL – No Observed (Adverse) Effect Level; NOELR – No Observable Effect Loading Rate; NTP – National Toxicology Program; NZIoC – New Zealand Inventory of Chemicals; OECD – Organization for Economic Co-operation and Development; OPPTS – Office of Chemical Safety and Pollution Prevention; PBT – Persistent, Bioaccumulative and Toxic substance; PICCS – Philippines Inventory of Chemicals and Chemical Substances; (Q) SAR – (Quantitative) Structure Activity Relationship; RCRA – Resource Conservation and Recovery Act; REACH – Regulation (EC) No 1907/2006 of the European Parliament and of the Council Concerning the Registration, Evaluation, Authorization and Restriction of Chemicals; RQ – Reportable Quantity; SADT – Self-Accelerating Decomposition Temperature; SARA – Superfund Amendments and Reauthorization Act; SDS – Safety Data Sheet; TCSI – Taiwan Chemical Substance Inventory; TSCA – Toxic Substance Control Act (United States); UN – United Nations; UNRTDG – United Nations Recommendations on the Transport of Dangerous Goods; vPvB – Very Persistent and Very Bioaccumulative.

Factor II, Inc.

This is to certify that the above designated material has been tested and did comply with the listed specifications (with listed exceptions) when supplied in original container. The material is subject to the conditions listed on the invoice. The above is a copy of information on file. The lot acceptance data are available for examination. This is a computer-generated document that is valid without a signature. The information above is supplied in good faith and, to the best of our knowledge, is based on available sources believed to be reliable and accurate. This document and any information provided herein are for your guidance only. The use by the requestor is beyond Factor II control; therefore, the responsibility for appropriate and safe use of the above information lies with the End user. Factor II shall not be responsible for any misuse and/or misapplication of the information in this document.

Factor II, Inc. urges each customer or recipient of this SDS to study it carefully to become aware of and understand the hazards associated with the product. The reader should consider consulting reference works or individuals who are experts in ventilation, toxicology and/or fire prevention as necessary or appropriate to the use and understanding of the data contained in this SDS. To promote safe handling each customer or recipient should 1) notify and furnish its employees, agents, contractors, customers and/or others whom it knows or believes will use this material of the information regarding hazards or safety, and 2) request its customers to notify their employees, customers and other users of the product of this information.