



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.

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| SECTION 1: IDENTIFICATION |
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PRODUCT IDENTIFIER

Product Name : Medical Silicone Adhesive

Product Code : A-100

Intended Use(s) : For professional use only. Adhesive/ binding agent.

CONTACT INFORMATION FOR SUPPLIER OF SAFETY DATA SHEET

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SECTION 2: HAZARD(S) IDENTIFICATION

Hazard Classification

This material is hazardous under the criteria of Federal OSHA Hazard Communication Standard 29CFR 1910.1200.

Reproductive toxicity – Category 2

Label Elements

Hazard Pictograms



Single Word: **WARNING!**

Hazards

Suspected of damaging fertility or the unborn child.

Precautionary Statements

Prevention

Obtain special instructions before use.

Do not handle until all safety precautions have been read and understood.

Wear protective gloves/ protective clothing/ eye protection/ Face protection.

Response

IF exposed or concerned: Get medical advice/ attention.

Storage

Store locked up.

Disposal

Dispose of contents/ container to an approved waste disposal plant.

Other Hazards

No data available

SECTION 3 : COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Nature : Silicone compound. This product is a mixture.

| Component | CASRN | Concentration |
|------------------------------|--------------|----------------------|
| Octamethylcyclotetrasiloxane | 556-67-2 | >= 0.26% - <= 0.35% |



SECTION 4: FIRST-AID MEASURES

Description of first aid measures

General Advice:

First Aid responders should pay attention to self-protection and use the recommended protective clothing (chemical resistant gloves, splash protection). 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 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 (below), any additional important symptoms and effects are described on 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 mixture

Hazardous combustion products: Carbon oxides Silicon oxides

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

Advice for Firefighters

Fire Fighting Procedures: Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations. Contain fire water run-off if possible. Fire water run-off, if not contained, may cause environmental damage. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool down unopened containers. Collect contaminated fire extinguishing water separately. This



must not be discharged into drains. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

Special protective equipment for firefighters: In the event of a 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 and recommendations.

Environmental precautions: Do not release the product to the aquatic environment above defined regulatory levels, 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: Wipe up or scrape up and contain for salvage or 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. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, sections 13 and 15 on 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: Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. 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 locked up. Store in accordance with the particular national regulations.

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



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.

| Component | Regulation | Type of listing | Value/notation |
|----------------------------------|-------------------|------------------------|-----------------------|
| Octamethyl Cyclotetrasiloxane | US WEEL | TWA | 10 ppm |

Although some of the components of this product may have exposure guidelines, no exposure would be expected under normal handling conditions due to the physical state of the material.

Exposure Controls

Engineering Controls: Use local exhaust ventilation, or to 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: 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 | paste |
| Color | White translucent |
| Odor | Acetic acid |
| Odor Threshold | No data available |
| pH | Not applicable |
| Melting Point/ range | No data available |
| Freezing Point | No data available |
| Boiling Point (760 mmHg) | Not applicable |
| Flash Point | closed up > 101.1 °C (> 214.0 °F) |
| Evaporation Rate (Butyl Acetate = 1) | Not applicable |
| Flammability (solid, gas) | Not classified as a flammability hazard |
| Lower Explosion Limit | No data available |
| Upper Explosion Limit | No data available |
| Vapor Pressure | Not applicable |
| Relative Vapor Density (air = 1) | No data available |
| Relative Density (water = 1) | 1.06 |
| 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 | Not applicable |
| Kinematic Viscosity | 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 |

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: 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

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

Prolonged exposure not likely to cause significant irritation.

Serious eye damage/ eye irritation

May cause slight temporary eye irritation.

Corneal injury is unlikely.

May cause mild eye discomfort.

Sensitization

For skin sensitization:

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)

Contains a component(s) that is/are encapsulated in the product and are not expected to be released under normal processing conditions or foreseeable emergency.

Carcinogenicity

For the major component(s): Did not cause cancer in long-term animal studies which used routes of exposure considered relevant to industrial handling. Positive results have been reported in other studies using routes of exposure not relevant to industrial handling.

Teratogenicity

Contains component(s) which did not cause birth defects in laboratory animals.

Reproductive Toxicity

Contains component(s) which have interfered with fertility in animal studies. Contains component(s) which have been shown to interfere with reproduction in animal studies.

Mutagenicity

In vitro genetic toxicity studies were negative.

Aspiration Hazard

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

COMPONENTS INFLUENCING TOXICOLOGY:

Octamethyl Cyclotetrasiloxane

Acute inhalation toxicity

LC50, Rat, male and female, 4 Hour, dust/mist, 36 mg/l OECD Test Guideline 403.

SECTION 12: ECOLOGICAL INFORMATION

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

Toxicity

Octamethyl Cyclotetrasiloxane

Acute toxicity to fish

Not expected to be acutely toxic to aquatic organisms.

No toxicity at the limit of solubility

LC50, Oncorhynchus mykiss (rainbow trout), flow-through, 96 Hour, >0.022 mg/l

No toxicity at the limit of solubility

LC50, Cyprinodon variegatus (sheepshead minnow), flow through, 14d, >0.0063 mg/l

Acute toxicity to aquatic invertebrates



No toxicity at the limit of solubility
EC50, Mysidopsis bahia (opossum shrimp), flow through test, 96 Hour, >0.0091 mg/l
No toxicity at the limit of solubility
EC50, Daphnia magna (water flea), flow through test, 48 Hour, >0.015 mg/l

Acute toxicity to algae/aquatic plants

No toxicity at the limit of solubility
ErC50, Pseudokirchneriella subcapitata (green algae), 72 Hour, Growth rate, >0.022 mg/l

Chronic toxicity to fish

No toxicity at the limit of solubility
NOEC, Oncorhynchus mykiss (rainbow trout), 93 d, >= 0.0044 mg/l

Chronic toxicity to aquatic invertebrates

No toxicity at the limit of solubility
NOEC, Daphnia magna (water flea), 21 d, >= 0.0079 mg/l

Persistence and Degradability

Octamethyl Cyclotetrasiloxane

Biodegradability: Material is expected to biodegrade very slowly (in the environment).
Fails to pass OECD/EEC test for ready biodegradability.

10-day window: Not applicable

Biodegradation: 3.7%

Exposure time: 28 d

Method: OECD Test Guideline 310

Stability in Water (1/2-life)

Hydrolysis, DT50, 69.3 – 144 Hour, pH 7, Half-life Temperature 24.6 °C, OECD Test Guideline 111

Photodegradation

Atmospheric half-life: 16 d

Method: Estimated.

Bioaccumulative potential

Octamethyl Cyclotetrasiloxane

Bioaccumulation: Bioconcentration potential is high (BCF > 3000 or Log Pow between 5 & 7).

Partition coefficient: n-octano/water(log Pow): 6.49 Measured.

Bioconcentration factor (BCF): 12,400 Pimephales promelas (fathead minnow)
Measured.

Mobility in soil

Octamethyl Cyclotetrasiloxane

Expected to be relatively immobile in soil (Koc > 5000).



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):

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

Reproductive toxicity

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

Calculated RQ Exceeds reasonably attainable upper limit.

| Components | CASRN | RQ (RCRA Code) |
|-------------|---------|----------------|
| Acetic acid | 64-19-7 | 5000 lbs RQ |

Pennsylvania Right-To-Know

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

| Components | CASRN |
|--|------------|
| Polydimethylsiloxane hydroxy-terminated | 70131-67-8 |
| Dimethyldichlorosilane reaction with silca | 68611-44-9 |

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.

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

Octamethylcyclotetrasiloxane (CAS 556-67-2)

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.



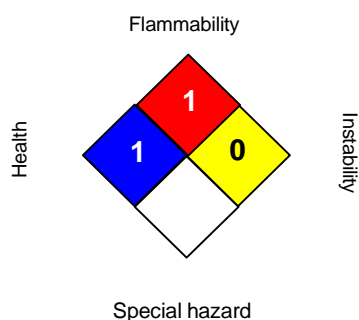
EU Medical Devices Regulation (MDR (EU) 2017/745)

Medical Silicone Adhesive 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

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).

Legend

| | |
|---------|---|
| TWA | 8-hr TWA |
| US WEEL | USA. Workplace Environmental Exposure Levels (WEEL) |

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 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.