

SAFETY DATA SHEET

According to Regulation 2012 OSHA Hazard Communication Standard: 29 CFR 1910.1200

1. Identification of the substance or mixture and of the supplier

1.1 Product identifier:

Product name: SILBIONE MED ADH 4100

Product No.: PRCO90054418

1.2 Relevant identified uses of the substance or mixture and uses advised against:

Identified uses: For molded or extruded healthcare and medical components.

Uses advised against: None known.

1.3 Details of the supplier of the safety data sheet:

Manufacturer:

Elkem Silicones USA Corp.
1615 Timberland Ct.
29745 York, SC
USA

Telephone: +1 (803) 792-3000

Fax: +1 (803) 684-7202

E-mail: product.stewardship@elkem.com

Supplier:

Elkem Silicones USA Corp.
Two Tower Blvd, Suite 1802
08816-1100 East Brunswick, NJ
USA

Telephone: +1 (732) 227-2060

Fax: +1 (732) 249-7000

1.4 Emergency telephone number:

+1 (800) 424-9300 CHEMTREC

2. Hazard identification

2.1 Classification of the substance or mixture:

The product has been classified according to the legislation in force.

Hazard Classification:

Health Hazards:

Skin irritation	Category 2	H315: Causes skin irritation.
Serious eye damage	Category 1	H318: Causes serious eye damage.
Toxic to reproduction	Category 2	H361f: Suspected of damaging fertility.

2.2 Label Elements:

Hazard pictograms:



Signal Word:

Danger

Hazard statements: H315: Causes skin irritation.
H318: Causes serious eye damage.
H361f: Suspected of damaging fertility.

Precautionary Statements:

Prevention: P280: Wear protective gloves/protective clothing/eye protection/face protection.

Response: P302+P350+P332+P313: IF ON SKIN: Wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention.
P305+P351+P315: IF IN EYES: Rinse cautiously with water for several minutes. Get immediate medical advice/attention.
P308+P313: IF exposed or concerned: Get medical advice/attention.

2.3 Other hazards which do not result in GHS classification:

Acetic acid is liberated on contact with moisture and living tissue.

Substance(s) formed under the conditions of use:

Chemical name	Concentration	CAS number	Classification
Acetic acid	<2%	64-19-7	Flam. Liq. 3 H227; Skin Corr. 1A H314; Eye Dam. 1 H318;

* All concentrations are percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

The full text for all H-statements is displayed in section 16.

3. Composition/information on ingredients

Mixtures:

General information:

Mixture of Polyorganosiloxanes, fillers, additives.

Hazardous Component(s):

Chemical name	Concentration *	Type	CAS number	Classification
Methylsilanetriyl triacetate	3 - 7%	Component	4253-34-3	Skin Corr. 1B H314; Eye Dam. 1 H318; Acute Tox. 4 H302;
Octamethylcyclotetrasiloxane	0.1 - <1%	Impurities	556-67-2	Flam. Liq. 3 H226; Repr. 2 H361f; Aquatic Chronic 1 H410; Aquatic Toxicity (Chronic): M = 10

* All concentrations are percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

The full text for all H-statements is displayed in section 16.

4. First-aid measures

General information:

Show this Safety Data Sheet to the attending physician.

4.1 Description of first aid measures:

Inhalation:

Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin Contact:

Wash skin with soap and water. Get medical attention if irritation persists after washing.

Eye contact:

In the event of contact with the eyes, rinse thoroughly with clean water for at least 15 minutes. Continue flushing for several additional minutes. Open eyes wide apart. Get medical attention immediately, preferably an ophthalmologist.

Ingestion:

Do not induce vomiting. Rinse mouth thoroughly. Call a POISON CENTER/doctor if you feel unwell.

Personal Protection for First-aid Responders:

First Aid responders should pay attention to self-protection and use the recommended protective clothing (chemical resistant gloves, splash protection). Refer to sections 5 and 8 for information on emergency procedures and protective equipment.

4.2 Most important symptoms and effects, both acute and delayed:

Any important symptoms and effects are described in Section 11 (Toxicological information) of this SDS.

4.3 Indication of any immediate medical attention and special treatment needed:**Notes to the physician:**

Treatment is symptomatic and supportive.

5. Fire-fighting measures**5.1 Extinguishing media:****Suitable extinguishing media:**

Water spray, foam, dry powder or carbon dioxide.

Unsuitable extinguishing media:

Do not use water jet as an extinguisher, as this will spread the fire.

5.2 Special hazards arising from the substance or mixture:

Product will burn under fire conditions. Thermal decomposition or combustion may liberate carbon oxides, silicon oxides and other toxic gases or vapors.

5.3 Advice for firefighters:**Special fire-fighting procedures:**

Use standard firefighting procedures and consider the hazards of other involved materials. Remove undamaged containers from fire area if it is safe to do so. Evacuate to a safe location and contact the emergency services. Water spray should be used to cool containers.

Special protective equipment for fire-fighters:

Firefighters should wear standard protective equipment and a positive pressure self-contained breathing apparatus (SCBA).

6. Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures:**

Provide good ventilation. Avoid inhalation of vapors, mists or dusts. Avoid contact with eyes, skin, and clothing. Prevent further leakage or spillage if safe to do so. Caution: Contaminated surfaces may be slippery.

6.2 Environmental Precautions:

Do not release into the environment. Do not discharge into drains, water courses or onto the ground.

6.3 Methods and material for containment and cleaning up:

Absorb with sand or other inert absorbent and place into containers.

6.4 Reference to other sections:

Please observe the important information mentioned in the other sections. In particular, information on exposure controls/personal protection and disposal considerations can be found under sections 8 and 13.

7. Handling and storage

7.1 Precautions for safe handling:

Precautions:

Avoid inhalation of vapors/aerosols/dusts and contact with skin and eyes. See Section 8 of the SDS for Personal Protective Equipment. Handle in accordance with good industrial hygiene and safety practices. Handle and open container with care. For further information, refer to section 10: "Stability and Reactivity". Take care to prevent spills, waste and minimize release to the environment. In case of spills, beware of slippery floors and surfaces.

Hygiene measures:

Provide eyewash station and safety shower.

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

7.2 Conditions for safe storage, including any incompatibilities:

Store in accordance with local/regional/national regulations. Store in a well-ventilated place. Keep container tightly closed. Keep in properly labelled containers.

Packaging frequently used at our sites:

Steel drums coated with epoxy-resin.

7.3 Specific end use(s):

See the technical data sheet on this product for further information.

8. Exposure controls/personal protection

8.1 Control Parameters:

Occupational Exposure Limits:

None of the components have assigned exposure limits.

Additional exposure limits under the conditions of use:

Acetic acid

Type	Exposure Limit Values	Source	Date	Remarks
STEL	15 ppm 37 mg/m3	NIOSH	2005	
TWA	10 ppm -	ACGIH	2008	
REL	10 ppm 25 mg/m3	NIOSH	2005	
PEL	10 ppm 25 mg/m3	OSHA Z1	02 2006	
TWA	10 ppm 25 mg/m3	OSHA Z1A	1989	
STEL	15 ppm -	ACGIH	2008	
IDLH	50 ppm -	NIOSH IDLH	10 2017	IDLH values based on the 1994 Revised Criteria

8.2 Exposure controls:

Appropriate Engineering Controls:

Provide adequate ventilation. In case of inadequate ventilation: Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Individual protection measures, such as personal protective equipment:

Avoid inhalation of vapors/aerosols/dusts and contact with skin and eyes. Personal protective equipment should be chosen according to applicable standards, adapted to the conditions of use of the product and in discussion with the supplier of the personal protective equipment.

Eye/face protection:	Goggles/face shield are recommended.
Hand Protection:	Impervious Protective Gloves
Skin and Body Protection:	Wear suitable protective clothing.
Respiratory Protection:	If ventilation is insufficient, suitable respiratory protection must be provided.

Environmental Controls:

See sections 7 and 13 of the Safety Data Sheet.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties:

Appearance:

Physical state:	Liquid
Form:	Paste
Color:	Colorless
Odor:	Acetic acid.
pH:	By definition, pH measurement consists in the determination of hydrogen ions concentration in solution, generally aqueous. Silicones products are hydrophobic and therefore, not soluble in water. By consequence, it is not possible to measure the pH value.
Melting point/freezing point:	< 0 °C
Boiling Point:	No data available.
Flash Point:	estimated > 94 °C / > 201 °F
Flammability:	No data available.
Flammability Limit - Upper (%):	No data available.
Flammability Limit - Lower (%):	No data available.
Vapor pressure:	No data available.
Relative vapor density:	No data available.
Evaporation Rate:	No data available.
Density:	Approximate 1.08 kg/dm ³ (20 °C)
Solubility(ies):	
Solubility in Water:	Insoluble
Solubility (other):	Acetone: Very slightly soluble Ethanol: Very slightly soluble Diethylether: Miscible (in all proportions). Aliphatic hydrocarbons: Miscible (in all proportions). Aromatic hydrocarbons: Miscible (in all proportions). Chlorinated solvents: Miscible (in all proportions).
Partition coefficient (n-octanol/water):	No data available.
Self Ignition Temperature:	No data available.

Decomposition Temperature: No data available.
Kinematic viscosity: No data available.

9.2 Other information:

Oxidizing properties: According to the data on the components
Not considered as oxidizing.
(according to EC criteria)

Particle Size: Not applicable

10. Stability and reactivity

10.1 Reactivity:

No other information noted.

10.2 Chemical Stability:

Stable in sealed containers stored under a dry inert atmosphere.

10.3 Possibility of hazardous reactions:

Reacts with water and moisture in air liberating acetic acid.

10.4 Conditions to avoid:

Avoid contact with water or moist air. The product hydrolyses and may release volatile flammable and/or toxic substance(s): Acetic acid. Avoid heat, sparks, open flames and other ignition sources.

10.5 Incompatible Materials:

Strong oxidizing agents. Alcohols. Strong alkalis.

10.6 Hazardous Decomposition Products:

Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapors. Amorphous silica.

11. Toxicological information

Information on likely routes of exposure: Human experience

Skin Contact:

Causes skin irritation.

Eye contact:

Causes serious eye damage.

11.1 Information on toxicological effects:

Acute toxicity:

Oral:

Not classified for acute toxicity based on available data.

Dermal:

Not classified for acute toxicity based on available data.

Inhalation:

Not classified for acute toxicity based on available data.

Repeated dose toxicity:

Based on our knowledge of the composition information:**METHYLSILANETRIYL TRIACETATE (4253-34-3):**

An Expert Judgment stated that no classification is necessary based on present knowledge. NOAEL: 50 mg/kg ; (Rat ; Female, Male ; Gavage (Oral)) ; Target Organ(s): stomach ; Method: OECD 422 ; Results obtained on a similar product.

OCTAMETHYLCYCLOTETRASILOXANE (556-67-2):

NOAEL: 1.82 mg/l ; LOAEL: 8.5 mg/l ; (Rat ; Female, Male ; Inhalation - vapour) ; Target Organ(s): Kidney ; Method: Similar to OECD 453 ; Chronic exposure.
NOAEL: 960 mg/kg ; (Rabbit ; Female, Male ; Dermal) ; No treatment-related adverse effects observed ; Method: Similar to OECD 410 ; Subacute exposure.

Skin Corrosion/Irritation:**Based on our knowledge of the composition information: Causes skin irritation.****METHYLSILANETRIYL TRIACETATE (4253-34-3):**

Causes severe skin burns and eye damage. Corrosive. (Rabbit ; 4 h) ; Method: OECD 404

OCTAMETHYLCYCLOTETRASILOXANE (556-67-2):

An Expert Judgment stated that no classification is necessary based on present knowledge. Not irritating (Rabbit) ; Method: Similar to OECD 404

Serious Eye Damage/Eye Irritation:**Based on our knowledge of the composition information: Causes serious eye damage.****METHYLSILANETRIYL TRIACETATE (4253-34-3):**

Causes serious eye damage. Corrosive. (Rabbit) ; Method: OECD 405

OCTAMETHYLCYCLOTETRASILOXANE (556-67-2):

An Expert Judgment stated that no classification is necessary based on present knowledge. Not irritating (Rabbit) ; Method: OECD 405

Respiratory or Skin Sensitization:**Based on our knowledge of the composition information:****METHYLSILANETRIYL TRIACETATE (4253-34-3):**

Skin sensitization: Not a skin sensitizer. ; Not a skin sensitizer. (Guinea Pig) ; Method: OECD 406

OCTAMETHYLCYCLOTETRASILOXANE (556-67-2):

Skin sensitization: Not a skin sensitizer. (Guinea Pig) ; Method: OECD 406

Germ Cell Mutagenicity:**In vitro: Based on our knowledge of the composition information:****METHYLSILANETRIYL TRIACETATE (4253-34-3):**

Bacteria: No mutagenic effect. (Salmonella typhimurium and Escherichia coli ; with and without metabolic activation) ; Method: OECD 471

In vitro gene mutations test on mammalian cells: No mutagenic effect. (Mouse lymphoma cells ; with and without metabolic activation) ; Method: OECD 476 ; Results obtained on a similar product.

Chromosomal aberration: No clastogenic effect. (Chinese hamster ovary cells ; with and without metabolic activation) ; Method: OECD 473

OCTAMETHYLCYCLOTETRASILOXANE (556-67-2):

Bacterial reverse mutation test: No mutagenic effect. (Salmonella typhimurium ; with and without metabolic activation) ; Method: OECD 471

In vitro gene mutations test on mammalian cells: No mutagenic effect. (Mouse lymphoma cells ; with and without metabolic activation) ; Method: Similar to OECD 476

In vitro mammalian chromosomal aberration test: No clastogenic effect. (Chinese hamster ovary cells ; with and without metabolic activation) ; Method: Similar to OECD 473

In vivo: Based on our knowledge of the composition information:

OCTAMETHYLCYCLOTETRASILOXANE (556-67-2):

Mammalian bone marrow chromosomal aberration test: negative (Rat ; Female, Male ; Inhalation) ; Method: Similar to OECD 475

Rodent dominant Lethal test: negative (Rat ; Female, Male ; Gavage (Oral)) ; Method: Similar to OECD 478

Carcinogenicity:

No data available.

IARC Monographs on the Evaluation of Carcinogenic Risks to Humans:

No carcinogens present or none present in regulated quantities

US. National Toxicology Program (NTP) Report on Carcinogens:

No carcinogens present or none present in regulated quantities

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050), as amended:

No carcinogens present or none present in regulated quantities

Reproductive toxicity:**Fertility: Based on our knowledge of the composition information: Suspected of damaging fertility.**

OCTAMETHYLCYCLOTETRASILOXANE (556-67-2):

Suspected of damaging fertility.

Fertility study 2 generations: NOAEL (parent): 3.64 mg/l ; NOAEL (F1): 3.64 mg/l ; NOAEL (F2): None. (Rat ; Female, Male ; Inhalation) ; Method: Similar to OECD 416 ; Effects on fertility

Teratogenicity: Based on our knowledge of the composition information: Suspected of damaging fertility.

OCTAMETHYLCYCLOTETRASILOXANE (556-67-2):

NOAEL (terato): > 8.492 mg/l ; NOAEL (mater): 3.64 mg/l (Rat ; Inhalation - vapor) ; Method: Similar to OECD 414 ; The product is not considered to be toxic for development.

NOAEL (terato): > 6.066 mg/l ; NOAEL (mater): 3.64 mg/l (Rabbit ; Inhalation - vapor) ; Method: Similar to OECD 414 ; The product is not considered to be toxic for development.

Specific Target Organ Toxicity - Single Exposure:**Based on our knowledge of the composition information:**

METHYLSILANETRIYL TRIACETATE (4253-34-3):

Corrosive to the respiratory tract.

OCTAMETHYLCYCLOTETRASILOXANE (556-67-2):

Based on available data, the classification criteria are not met.

Specific Target Organ Toxicity - Repeated Exposure:**Based on our knowledge of the composition information:**

METHYLSILANETRIYL TRIACETATE (4253-34-3):

Based on available data, the classification criteria are not met.

OCTAMETHYLCYCLOTETRASILOXANE (556-67-2):

Based on available data, the classification criteria are not met.

Aspiration Hazard:**Based on our knowledge of the composition information:**

METHYLSILANETRIYL TRIACETATE (4253-34-3):

Based on available data, the classification criteria are not met.

OCTAMETHYLCYCLOTETRASILOXANE (556-67-2):
Based on available data, the classification criteria are not met.

12. Ecological information

General information:

The maximum concentration of Octamethylcyclotetrasiloxane (D4) in the aquatic environment is estimated to be below the established no-effect threshold (<0.0079 mg/l) for aquatic organisms (based on partition coefficient, tested on similar products).

12.1 Ecotoxicity:

Acute toxicity:

Fish: Based on our knowledge of the composition information:

METHYLSILANETRIYL TRIACETATE (4253-34-3):

LC 50 (96 h) : > 100 mg/l ; Results obtained on a similar product.

OCTAMETHYLCYCLOTETRASILOXANE (556-67-2):

LC 50 (Oncorhynchus mykiss; 96 h ; Flow through) : > 0.022 mg/l ; Method: According to a standardised method.

Aquatic Invertebrates: Based on our knowledge of the composition information:

METHYLSILANETRIYL TRIACETATE (4253-34-3):

LC 50 (48 h) : > 100 mg/l ; Results obtained on a similar product.

OCTAMETHYLCYCLOTETRASILOXANE (556-67-2):

EC 50 (Water flea (Daphnia magna); 48 h ; Flow through) : > 0.015 mg/l ; Method: According to a standardised method.

Aquatic plants: Based on our knowledge of the composition information:

METHYLSILANETRIYL TRIACETATE (4253-34-3):

EC 50 (96 h) : 660 mg/l ; Results obtained on a similar product.

OCTAMETHYLCYCLOTETRASILOXANE (556-67-2):

ErC50 (Algae (Pseudokirchneriella subcapitata); 96 h) : > 0.022 mg/l ; Method: According to a standardised method.

ErC10 (Algae (Pseudokirchneriella subcapitata); 96 h) : >= 0.022 mg/l ; Method: According to a standardised method.

Toxicity to microorganisms: Based on our knowledge of the composition information:

OCTAMETHYLCYCLOTETRASILOXANE (556-67-2):

EC 50 (3 h) : > 10,000 mg/l

Chronic Toxicity:

Fish: Based on our knowledge of the composition information:

OCTAMETHYLCYCLOTETRASILOXANE (556-67-2):

NOEC (Oncorhynchus mykiss; 93 d ; Flow through) : >= 0.0044 mg/l ; Method: According to a standardised method.

Aquatic Invertebrates: Based on our knowledge of the composition information:

OCTAMETHYLCYCLOTETRASILOXANE (556-67-2):

NOEC (Water flea (Daphnia magna); 21 d ; Flow through) : >= 0.015 mg/l ; Method: According to a standardised method.

12.2 Persistence and Degradability:

Stability in water: No data available.

Biodegradation: Based on our knowledge of the composition information:

METHYLSILANETRIYL TRIACETATE (4253-34-3):

74 % (activated sludge, domestic, non-adapted ; 21 d ; Dissolved organic carbon (DOC)) ; Method: According to a standardised method. ; Readily biodegradable Results obtained on a similar product.

OCTAMETHYLCYCLOTETRASILOXANE (556-67-2):

3.7 % (activated sludge and sewage, soil ; 28 d) ; Method: OECD 310 ; The product is not considered to be readily biodegradable.

BOD/COD Ratio: No data available.

12.3 Bioaccumulative potential:

Bioconcentration Factor (BCF): Based on our knowledge of the composition information:

OCTAMETHYLCYCLOTETRASILOXANE (556-67-2):

Bioconcentration Factor (BCF): 14,900 (Fathead Minnow) ; Method: OECD 305 ; Not bioaccumulable based on the depuration rate constant

Partition coefficient (n-octanol/water): Based on our knowledge of the composition information:

METHYLSILANETRIYL TRIACETATE (4253-34-3):

Log Kow: -2.4 ; Method: estimated

12.4 Mobility in soil:

No data available.

12.5 Other adverse effects:

No data available.

13. Disposal considerations

13.1 Waste treatment methods:

The user's attention is drawn to the possible existence of local regulations regarding disposal.

Disposal methods:

Dispose of waste at an appropriate treatment and disposal facility in accordance with applicable laws and regulations, and product characteristics at time of disposal.

Contaminated Packaging:

Contaminated packages should be as empty as possible. Recycle following cleaning or dispose of at an authorised site. Packaging that cannot be cleaned should be disposed of in the same way as the product it contained.

14. Transport information

DOT

Not regulated.

IMDG / IMO

Not regulated.

IATA

Not regulated.

15. Regulatory information

US Federal Regulations:

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D): None present or none present in regulated quantities.

CERCLA Hazardous Substance List (40 CFR 302.4): None present or none present in regulated quantities.

Superfund Amendments and Reauthorization Act of 1986 (SARA):

Hazard categories:

Skin Corrosion/Irritation, Serious Eye Damage/Eye Irritation, Toxic to reproduction

SARA 304 Emergency Release Notification: None present or none present in regulated quantities.

US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 313 Toxic Chemicals (40 CFR 372.65) - Supplier Notification Required: None present or none present in regulated quantities.

US State Regulations:

US. California Proposition 65: No ingredient requiring a warning under CA Prop 65.

US. New Jersey Worker and Community Right-to-Know Act: No ingredient regulated by NJ Right-to-Know Law present.

US. Massachusetts RTK - Substance List: No ingredient regulated by MA Right-to-Know Law present.

US. Pennsylvania RTK - Hazardous Substances: No ingredient regulated by PA Right-to-Know Law present.

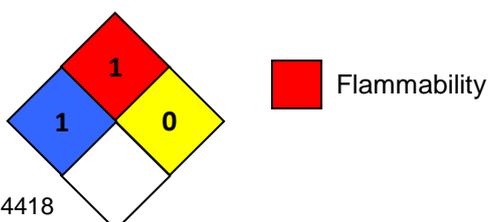
US. Rhode Island RTK: No ingredient regulated by RI Right-to-Know Law present.

Inventory Status:

Australia Industrial Chem. Act (AIC):	On or in compliance with the inventory.
Canada DSL Inventory List:	On or in compliance with the inventory.
China Inv. Existing Chemical Substances:	On or in compliance with the inventory.
Japan (ENCS) List:	On or in compliance with the inventory.
Korea Existing Chemicals Inv. (KECI):	On or in compliance with the inventory.
New Zealand Inventory of Chemicals:	On or in compliance with the inventory.
Philippines PICCS:	On or in compliance with the inventory.
Taiwan Chemical Substance Inventory:	On or in compliance with the inventory.
US TSCA Inventory:	On or in compliance with the inventory.
Thailand DIW Existing Chemical Inv. List:	On or in compliance with the inventory.
Vietnam National Chemical Inventory:	On or in compliance with the inventory.
EINECS, ELINCS or NLP:	On or in compliance with the inventory.

16. Other information, including date of preparation or last revision

NFPA Hazard ID:



	Health
	Reactivity
	Special hazard.

Hazard rating: 0 - Minimal; 1 - Slight; 2 - Moderate; 3 - Serious; 4 - Severe; RNP - Rating not possible

Wording of the H-statements in section 2 and 3:

H226	Flammable liquid and vapor.
H227	Combustible liquid.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H361f	Suspected of damaging fertility.
H410	Very toxic to aquatic life with long lasting effects.

Issue Date: 11/17/2022

Version #: 6.3

Further Information:

No data available.

Disclaimer:

The information given is based on data available for the material, the components of the material, and similar materials. The information is believed to be correct. It is given in good faith. This information should be used to make an independent determination of the methods to safeguard workers and the environment.