

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 RTV 4510 B U1

Product No.: PRCO90060772

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: Not for implantation in the body for >29 days.

1.3 Details of the supplier of the safety data sheet:

Manufacturer:

Elkem Silicones USA Corp.
7979 Park Place Road
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. Hazards identification

2.1 Classification of the substance or mixture:

The product has not been classified as hazardous according to the legislation in force.

Hazard Classification: Not classified

2.2 Label Elements:

Hazard pictograms:	No symbol.
Signal Word:	No signal word.
Hazard statements:	Not applicable.
Precautionary Statements:	
Prevention:	Not applicable: Not applicable.
Response:	Not applicable: Not applicable.
Storage:	Not applicable: Not applicable.

Disposal: Not applicable: Not applicable.

2.3 Other hazards which do not result in GHS classification:

Chemical compounds containing silicon - hydrogen bonds (SiH). This product may generate hydrogen gas. For further information, refer to section 10: "Stability and Reactivity".

3. Composition/information on ingredients

Mixtures:

General information:

Mixture of Polyorganosiloxanes, fillers.

4. First-aid measures

General information:

For further information refer to section 8 "Exposure-controls/personal protection".

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 thoroughly with soap and water. Get medical attention if symptoms occur after washing.

Eye contact:

In the event of contact with the eyes, rinse thoroughly with clean water for at least 15 minutes. Get medical attention if irritation persists after washing.

Ingestion:

Do not induce vomiting.
Rinse mouth thoroughly.
Get medical attention if symptoms occur.

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

None known.

4.3 Indication of any immediate medical attention and special treatment needed:

Hazards:

No specific recommendations.

Treatment:

No specific recommendations.

5. Fire-fighting measures

General Fire Hazards:

Water spray should be used to cool containers.

5.1 Extinguishing media:

Suitable extinguishing media:

Dry chemical, alcohol resistant foam or carbon dioxide (CO₂).

Unsuitable extinguishing media:

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

5.2 Special hazards arising from the substance or mixture:

Product will burn under fire conditions. This product may generate hydrogen gas. Vapors may form explosive mixtures with air. For further information, refer to section 10: "Stability and Reactivity". Hazardous Decomposition Products : formaldehyde, oxides of carbon and silica.

5.3 Advice for firefighters:

Special fire fighting procedures:

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:

Wear appropriate personal protective equipment. See Section 8 of the SDS for Personal Protective Equipment. Avoid contact with alkalis and caustic products. Eliminate all sources of ignition.

6.2 Environmental Precautions:

Collect spillage. Prevent entry into waterways, sewer, basements or confined areas. Mechanically ventilate the spillage area to prevent the formation of explosive concentrations.

6.3 Methods and material for containment and cleaning up:

Absorb with sand or other inert absorbent. Avoid contact with bases. Use clean non-sparking tools to collect absorbed material. Ensure that waste and contaminated materials are collected and removed from the work area as soon as possible in a suitably labeled container. Suitable containers: equipped with a degassing device.

6.4 Reference to other sections:

Caution: Contaminated surfaces may be slippery. For waste disposal, see Section 13 of the SDS.

7. Handling and storage

7.1 Precautions for safe handling:

Precautions:

Use mechanical ventilation in case of handling which causes formation of vapors.

Do not mix with incompatible materials. For further information, refer to section 10: "Stability and Reactivity".

Read and follow manufacturer's recommendations.

Hygiene measures:

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 original vented container. Store in a cool, dry place with adequate ventilation. Keep away from incompatible materials, open flames, and high temperatures.

7.3 Specific end use(s):

No data available.

8. Exposure controls/personal protection

8.1 Control Parameters:

Occupational Exposure Limits:

None of the components have assigned exposure limits.

8.2 Exposure controls:

Appropriate Engineering Controls:

No specific recommendations.

Individual protection measures, such as personal protective equipment:

Provide sufficient ventilation during operations which cause vapor formation.

This product can form formaldehyde vapors when heated to temperatures above 150 degrees C in the presence of air.

Eye/face protection:	Wear approved chemical safety glasses.
Hand Protection:	Material: Protective gloves are recommended.
Skin and Body Protection:	Wear suitable protective clothing.
Respiratory Protection:	No protection is ordinarily required under normal conditions of use and with adequate ventilation.

Environmental Controls:

No data available.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties:

Appearance:

Physical state:	Liquid
Form:	Viscous
Color:	Colorless
Odor:	Faint
Odor Threshold:	No data available.
pH:	Not applicable.
Melting point/freezing point:	No data available.
Boiling Point:	No data available.
Flash Point:	> 180 °C (Closed cup according to method Afnor T 60103.)
Evaporation Rate:	No data available.
Flammability (solid, gas):	No data available.
Flammability Limit - Upper (%):	74 %(V) Hydrogen.
Flammability Limit - Lower (%):	4 %(V) Hydrogen.
Vapor pressure:	No data available.
Vapor density (air=1):	No data available.
Density:	Approximate 1.10 g/cm ³ (20 °C)
Solubility(ies):	
Solubility in Water:	Insoluble
Solubility (other):	No data available.
Partition coefficient (n-octanol/water):	No data available.
Self Ignition Temperature:	500 °C Hydrogen.
Decomposition Temperature:	No data available.
Kinematic viscosity:	Approximate 1,300 mm ² /s (25 °C)

Dynamic viscosity: No data available.
Explosive properties: No data available.
Oxidizing properties: No data available.

9.2 Other information: No data available.

10. Stability and reactivity

10.1 Reactivity:

No other information noted.

10.2 Chemical Stability:

Material is stable under normal conditions.

10.3 Possibility of hazardous reactions:

This product may generate hydrogen gas.

10.4 Conditions to avoid:

Avoid heat, sparks, open flames and other ignition sources.

10.5 Incompatible Materials:

A fire or explosion hazard arises because highly flammable gas (hydrogen) is released when it is in contact with : Strong oxidizers, strong bases and chemical compounds with mobile hydrogen, in the presence of metal salts and complexes.

10.6 Hazardous Decomposition Products:

This product can form formaldehyde vapors when heated to temperatures above 150 degrees C in the presence of air. Thermal decomposition or combustion may liberate carbon oxides, other toxic gases or vapors and amorphous silica.

Quantity of hydrogen potentially released (l/kg of product): < 5

11. Toxicological information

Information on likely routes of exposure:

Inhalation:

No effects expected (assessment based on ingredients).

Ingestion:

No effects expected (assessment based on ingredients).

Skin contact:

No effects expected (assessment based on ingredients).

Eye contact:

No effects expected (assessment based on ingredients).

11.1 Information on toxicological effects:

Acute toxicity:

Oral:

Not classified for acute toxicity based on available data.

Dermal:

ATEmix : 10,155.07 mg/kg

Inhalation:

No effects expected (assessment based on ingredients).

Repeated dose toxicity:

No effects expected (assessment based on ingredients).

Skin Corrosion/Irritation:

No effects expected (assessment based on ingredients).

Serious Eye Damage/Eye Irritation:

No effects expected (assessment based on ingredients).

Respiratory or Skin Sensitization:

No effects expected (assessment based on ingredients).

Germ Cell Mutagenicity:

In vitro:

No effects expected (assessment based on ingredients).

In vivo:

No effects expected (assessment based on ingredients).

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:

No effects expected (assessment based on ingredients).

No data available.

Teratogenicity: No data available.

Specific Target Organ Toxicity - Single Exposure:

No effects expected (assessment based on ingredients).

Specific Target Organ Toxicity - Repeated Exposure:

No effects expected (assessment based on ingredients).

Aspiration Hazard:

No effects expected (assessment based on ingredients).

12. Ecological information

12.1 Toxicity:

Acute toxicity:

Fish:

No effects expected (assessment based on ingredients).

Aquatic Invertebrates:

No effects expected (assessment based on ingredients).

Aquatic plants:

No effects expected (assessment based on ingredients).

Toxicity to microorganisms: No data available.

Chronic Toxicity:

Fish:

No effects expected (assessment based on ingredients).

Aquatic Invertebrates:

No effects expected (assessment based on ingredients).

12.2 Persistence and Degradability:

Biodegradation:

The product is not biodegradable.

BOD/COD Ratio:

Not determined.

12.3 Bioaccumulative potential:

Bioconcentration Factor (BCF):

The product is not bioaccumulating.

Partition coefficient (n-octanol/water): No data available.

12.4 Mobility in soil:

No data available.

12.5 Other adverse effects:

None known.

13. Disposal considerations

13.1 Waste treatment methods:

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. Waste of this material should not be mixed with other waste. Provide measures such as vented bungs to ensure pressure relief in the waste container.

Contaminated packages should be as empty as possible and equipped with a degassing device.

Contaminated Packaging:

No data available.

14. Transport information

This material is not subject to transport regulations.

Other information:

Packaging with a breathing/venting bung are FORBIDDEN for transport by air.

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:

SARA 304 Emergency Release Notification:

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:

US TSCA Inventory:	On or in compliance with the inventory.
Canada DSL Inventory List:	On or in compliance with the inventory.
EINECS, ELINCS or NLP:	On or in compliance with the inventory.
China Inv. Existing Chemical Substances:	On or in compliance with the inventory.

Korea Existing Chemicals Inv. (KECI):
 Australia AICS:
 Philippines PICCS:
 New Zealand Inventory of Chemicals:

On or in compliance with the inventory.
 On or in compliance with the inventory.
 On or in compliance with the inventory.
 On or in compliance with the inventory.

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

HMIS Hazard ID:

Health	1
Flammability	1
Physical Hazards	1
PERSONAL PROTECTION	
	B

Hazard rating: 0 - Minimal; 1 - Slight; 2 - Moderate; 3 - Serious; 4 - Severe; RNP - Rating not possible; *Chronic health effect
 B - Safety Glasses & Gloves

NFPA Hazard ID:



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

Issue Date: 10/13/2020

Version #: 5.0

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.