

SAFETY DATA SHEET

1. Identification

Product identifier: SILBIONE RTV 4410 A

Recommended use and restriction on use

Recommended use: For molded or extruded healthcare and medical components.

Restrictions on use: Not for implantation in the body.



Manufacturer/Importer/Supplier/Distributor Information

Manufacturer

Company Name: Elkem Silicones USA Corp.
Address: 7979 Park Place Road
29745 York, SC
Telephone: +1 (803) 792-3000
Fax: +1 (803) 684-7202
Contact Person:
E-mail: product.stewardship@elkem.com

Supplier

Company Name: Elkem Silicones USA Corp.
Address: Two Tower Blvd, Suite 1601
08816-1100 East Brunswick, NJ
Telephone: +1 (732) 227-2060
Fax: +1 (732) 249-7000

Emergency telephone number: +1 (800) 424-9300 CHEMTREC

2. Hazard(s) identification

Hazard Classification

Not a hazardous substance or mixture according to GHS.

Label Elements

Hazard Symbol: No symbol.
Signal Word: No signal word.
Hazard Statement: Not applicable

Precautionary Statements

Prevention: Not applicable
Response: Not applicable
Storage: Not applicable
Disposal: Not applicable

Other hazards which do not result in GHS classification: No data available.

3. Composition/information on ingredients

Mixtures

Composition Comments: Mixture of Polyorganosiloxanes, fillers, additives.

4. First-aid measures

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

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

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

Skin Contact: Wash contact areas 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. Continue to rinse for at least 15 minutes. Get medical attention if irritation persists after washing.

Most important symptoms/effects, acute and delayed

Symptoms: None known.

Hazards: No specific recommendations.

Indication of immediate medical attention and special treatment needed

Treatment: No specific recommendations.

5. Fire-fighting measures

General Fire Hazards: No specific recommendations.

Suitable (and unsuitable) extinguishing media

Suitable extinguishing media: Water spray, foam, dry powder or carbon dioxide.

Unsuitable extinguishing media: None known.

Specific hazards arising from the chemical: Product will burn under fire conditions. Hazardous Decomposition Products : formaldehyde, oxides of carbon and silica.

Special protective equipment and precautions 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

Personal precautions, protective equipment and emergency procedures: Wear appropriate personal protective equipment. See Section 8 of the SDS for Personal Protective Equipment.

Methods and material for containment and cleaning up: Absorb with sand or other inert absorbent and place into containers.

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

Environmental Precautions: Do not allow to enter drains, sewers or watercourses.

7. Handling and storage

Precautions for safe handling: No specific precautions.

Conditions for safe storage, including any incompatibilities: No special storage precautions noted.

8. Exposure controls/personal protection

Control Parameters

Occupational Exposure Limits

None of the components have assigned exposure limits.

Appropriate Engineering Controls No specific recommendations.

Individual protection measures, such as personal protective equipment

General information: Provide sufficient ventilation during operations which cause vapor formation.

Eye/face protection: Safety Glasses.

Skin Protection

Hand Protection: Protective gloves are recommended.

Other: Wear suitable protective clothing.

Respiratory Protection: No protection is ordinarily required under normal conditions of use and with adequate ventilation.

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.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties:

Appearance

Physical state:	Liquid
Form:	Slightly viscous
Color:	Colorless
Odor:	Odorless
Odor threshold:	No data available.
pH:	Not applicable
Freezing point:	No data available.
Boiling Point:	No data available.
Flash Point:	> 392 °F (200 °C) Approximate
Evaporation rate:	No data available.
Flammability (solid, gas):	No data available.
Flammability limit - upper (%):	No data available.
Flammability limit - lower (%):	No data available.
Vapor pressure:	No data available.
Vapor density:	No data available.
Density:	Approximate 1.1 kg/dm ³ (68 °F (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.
Auto-ignition temperature:	No data available.
Decomposition temperature:	No data available.
Viscosity:	Approximate 2,000 - 3,000 mm ² /s
Other information	
Oxidizing properties:	According to the data on the components Not considered as oxidizing. (according to EC criteria)

10. Stability and reactivity

Reactivity:	No data available.
Chemical Stability:	Stable
Possibility of hazardous reactions:	Will not occur.
Conditions to avoid:	No other information noted.
Incompatible Materials:	Strong oxidizing agents.
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.

11. Toxicological information

Information on likely routes of exposure

Ingestion:	No effects expected (assessment based on ingredients).
Inhalation:	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).

Symptoms related to the physical, chemical and toxicological characteristics

Ingestion:	No data available.
Inhalation:	No data available.
Skin Contact:	No data available.
Eye contact:	No data available.

Information on toxicological effects

Acute toxicity (list all possible routes of exposure)

Oral	
Product:	No data available.
Dermal	
Product:	No data available.
Inhalation	
Product:	No data available.

Repeated dose toxicity	
Product:	No effects expected (assessment based on ingredients).

Skin Corrosion/Irritation	
Product:	No effects expected (assessment based on ingredients).

Serious Eye Damage/Eye Irritation	
Product:	No effects expected (assessment based on ingredients).

Respiratory or Skin Sensitization	
Product:	No effects expected (assessment based on ingredients).

Carcinogenicity	
Product:	No effects expected (assessment based on ingredients).

IARC Monographs on the Evaluation of Carcinogenic Risks to Humans:
No carcinogenic components identified

US. National Toxicology Program (NTP) Report on Carcinogens:
No carcinogenic components identified

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050):
No carcinogenic components identified

Germ Cell Mutagenicity

In vitro

Product: No effects expected (assessment based on ingredients).

In vivo

Product: No effects expected (assessment based on ingredients).

Reproductive toxicity

Product: No effects expected (assessment based on ingredients).

Specific Target Organ Toxicity - Single Exposure

Product: No effects expected (assessment based on ingredients).

Specific Target Organ Toxicity - Repeated Exposure

Product: No effects expected (assessment based on ingredients).

Aspiration Hazard

Product: No effects expected (assessment based on ingredients).

Other effects: None known.

12. Ecological information

Ecotoxicity:

Acute hazards to the aquatic environment:

Fish

Product: No effects expected (assessment based on ingredients).

Aquatic Invertebrates

Product: No effects expected (assessment based on ingredients).

Chronic hazards to the aquatic environment:

Fish

Product: No effects expected (assessment based on ingredients).

Aquatic Invertebrates

Product: No effects expected (assessment based on ingredients).

Toxicity to Aquatic Plants

Product: No effects expected (assessment based on ingredients).

Persistence and Degradability

Biodegradation

Product: The product is not readily biodegradable.

BOD/COD Ratio

Product: No data available.

Bioaccumulative potential

Bioconcentration Factor (BCF)

Product: The product is not bioaccumulating.

Partition Coefficient n-octanol / water (log Kow)

Product: No data available.

Mobility in soil: No data available.

Other adverse effects: None known.

13. Disposal considerations

Disposal instructions: 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 packages should be as empty as possible.

14. Transport information

This material is not subject to transport regulations.

Environmental hazards: Not regulated.

Special precautions for user: No special precautions.

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

☐ Acute (Immediate) ☐ Chronic (Delayed) ☐ Fire ☐ Reactive ☐ Pressure Generating

SARA 302 Extremely Hazardous Substance
None present or none present in regulated quantities.

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

SARA 313 (TRI Reporting)
None present or none present in regulated quantities.

Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3)
None present or none present in regulated quantities.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130):
None present or none present in regulated quantities.

US State Regulations

US. California Proposition 65

No ingredient regulated by CA Prop 65 present.

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):	On or in compliance with the inventory.
Australia AICS:	On or in compliance with the inventory.
Philippines PICCS:	On or in compliance with the inventory.
New Zealand Inventory of Chemicals:	On or in compliance with the inventory.

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

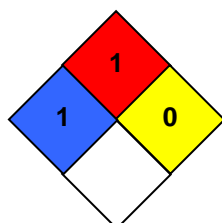
HMIS Hazard ID

Health	1
Flammability	1
Physical Hazards	0
PERSONAL PROTECTION	B

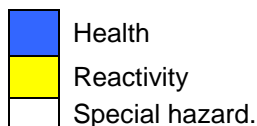
B - Safety Glasses & Gloves

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

NFPA Hazard ID



 Flammability



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

Issue Date: 07/10/2018

Revision Date: No data available.

Version #: 6.0

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.

SAFETY DATA SHEET

1. Identification

Product identifier: SILBIONE RTV 4410 B

Recommended use and restriction on use

Recommended use: For molded or extruded healthcare and medical components.

Restrictions on use: Not for implantation in the body.

Manufacturer/Importer/Supplier/Distributor Information

Manufacturer

Company Name: Elkem Silicones USA Corp.
Address: 7979 Park Place Road
29745 York, SC
Telephone: +1 (803) 792-3000
Fax: +1 (803) 684-7202
Contact Person:
E-mail: product.stewardship@elkem.com

Supplier

Company Name: Elkem Silicones USA Corp.
Address: Two Tower Blvd, Suite 1601
08816-1100 East Brunswick, NJ
Telephone: +1 (732) 227-2060
Fax: +1 (732) 249-7000

Emergency telephone number: +1 (800) 424-9300 CHEMTREC

2. Hazard(s) identification

Hazard Classification

Not a hazardous substance or mixture according to GHS.

Label Elements

Hazard Symbol: No symbol.
Signal Word: No signal word.
Hazard Statement: Not applicable

Precautionary Statements

Prevention: Not applicable
Response: Not applicable
Storage: Not applicable
Disposal: Not applicable

Other hazards which do not result in GHS classification:

Chemical compounds containing silicon - hydrogen bonds (SiH).

3. Composition/information on ingredients

Mixtures

Composition Comments: Mixture of Polyorganosiloxanes, fillers.

4. First-aid measures

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

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

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.

Most important symptoms/effects, acute and delayed

Symptoms: None known.

Hazards: No specific recommendations.

Indication of immediate medical attention and special treatment needed

Treatment: No specific recommendations.

5. Fire-fighting measures

General Fire Hazards: No specific recommendations.

Suitable (and unsuitable) 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.

Specific hazards arising from the chemical: Product will burn under fire conditions. Hazardous Decomposition Products : formaldehyde, oxides of carbon and silica.

Special protective equipment and precautions 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

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.
Methods and material for containment and cleaning up:	Avoid contact with alkalis and caustic products. Absorb with sand or other inert absorbent and place into containers.
Notification Procedures:	Caution: Contaminated surfaces may be slippery. For waste disposal, see Section 13 of the SDS.
Environmental Precautions:	Do not allow to enter drains, sewers or watercourses.

7. Handling and storage

Precautions for safe handling:	Provide sufficient ventilation during operations which cause vapor formation. Do not mix with incompatible materials. For further information, refer to section 10: "Stability and Reactivity". Read and follow manufacturer's recommendations.
Conditions for safe storage, including any incompatibilities:	Store in tightly closed original container. Store in a cool, dry place with adequate ventilation. Keep away from incompatible materials, open flames, and high temperatures.

8. Exposure controls/personal protection

Control Parameters

Occupational Exposure Limits

None of the components have assigned exposure limits.

Appropriate Engineering Controls

No specific recommendations.

Individual protection measures, such as personal protective equipment

General information:	Provide sufficient ventilation during operations which cause vapor formation.
Eye/face protection:	Safety Glasses.
Skin Protection	
Hand Protection:	Protective gloves are recommended.
Other:	Wear suitable protective clothing.
Respiratory Protection:	No protection is ordinarily required under normal conditions of use and with adequate ventilation.
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.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties:**Appearance**

Physical state:	Liquid
Form:	Slightly viscous
Color:	Colorless
Odor:	Odorless
Odor threshold:	No data available.
pH:	Not applicable
Freezing point:	No data available.
Boiling Point:	No data available.
Flash Point:	> 392 °F (200 °C) (Closed Cup)
Evaporation rate:	No data available.
Flammability (solid, gas):	No data available.
Flammability limit - upper (%):	No data available.
Flammability limit - lower (%):	No data available.
Vapor pressure:	No data available.
Vapor density:	No data available.
Density:	Approximate 1.1 kg/dm ³ (68 °F (20 °C))
Solubility(ies)	
Solubility in water:	Insoluble
Solubility (other):	Acetone: Very slightly soluble. Alcohol: 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.
Auto-ignition temperature:	No data available.
Decomposition temperature:	No data available.
Viscosity:	Approximate 2,000 - 3,000 mm ² /s
Other information	
Oxidizing properties:	According to the data on the components Not considered as oxidizing. (evaluation by structure-activity relationship)

10. Stability and reactivity

Reactivity:	No data available.
Chemical Stability:	Material is stable under normal conditions.
Possibility of hazardous reactions:	This product may generate hydrogen gas.
Conditions to avoid:	No other information noted.
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.

**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): < 2

11. Toxicological information**Information on likely routes of exposure**

Ingestion: No effects expected (assessment based on ingredients).

Inhalation: 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).

Symptoms related to the physical, chemical and toxicological characteristics

Ingestion: No data available.

Inhalation: No data available.

Skin Contact: No data available.

Eye contact: No data available.

Information on toxicological effects**Acute toxicity (list all possible routes of exposure)****Oral**

Product: No data available.

Dermal

Product: No data available.

Inhalation

Product: No data available.

Repeated dose toxicity

Product: No effects expected (assessment based on ingredients).

Skin Corrosion/Irritation

Product: No effects expected (assessment based on ingredients).

Serious Eye Damage/Eye Irritation

Product: No effects expected (assessment based on ingredients).

Respiratory or Skin Sensitization

Product: No effects expected (assessment based on ingredients).

Carcinogenicity

Product: No effects expected (assessment based on ingredients).

IARC Monographs on the Evaluation of Carcinogenic Risks to Humans:

No carcinogenic components identified

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

No carcinogenic components identified

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

No carcinogenic components identified

Germ Cell Mutagenicity

In vitro

Product: No effects expected (assessment based on ingredients).

In vivo

Product: No effects expected (assessment based on ingredients).

Reproductive toxicity

Product: No effects expected (assessment based on ingredients).

Specific Target Organ Toxicity - Single Exposure

Product: No effects expected (assessment based on ingredients).

Specific Target Organ Toxicity - Repeated Exposure

Product: No effects expected (assessment based on ingredients).

Aspiration Hazard

Product: No effects expected (assessment based on ingredients).

Other effects: None known.

12. Ecological information

Ecotoxicity:

Acute hazards to the aquatic environment:

Fish

Product: No effects expected (assessment based on ingredients).

Aquatic Invertebrates

Product: No effects expected (assessment based on ingredients).

Chronic hazards to the aquatic environment:

Fish

Product: No effects expected (assessment based on ingredients).

Aquatic Invertebrates

Product: No effects expected (assessment based on ingredients).

Toxicity to Aquatic Plants

Product: No effects expected (assessment based on ingredients).

Persistence and Degradability

Biodegradation

Product: Not applicable

BOD/COD Ratio**Product:** No data available.**Bioaccumulative potential****Bioconcentration Factor (BCF)****Product:** No data available.**Partition Coefficient n-octanol / water (log Kow)****Product:** No data available.**Mobility in soil:** No data available.**Other adverse effects:** None known.**13. Disposal considerations**

Disposal instructions: 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. Contaminated packages should be as empty as possible.

14. Transport information

This material is not subject to transport regulations.

Environmental hazards: Not regulated.**Special precautions for user:** No special precautions.**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**☐ Acute (Immediate) ☐ Chronic (Delayed) ☐ Fire ☐ Reactive ☐ Pressure Generating**SARA 302 Extremely Hazardous Substance**

None present or none present in regulated quantities.

SARA 304 Emergency Release Notification

None present or none present in regulated quantities.

SARA 313 (TRI Reporting)

None present or none present in regulated quantities.

Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3)

None present or none present in regulated quantities.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130):

None present or none present in regulated quantities.

US State Regulations

US. California Proposition 65

No ingredient regulated by CA Prop 65 present.

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.
Japan (ENCS) List:	On or in compliance with the inventory.
China Inv. Existing Chemical Substances:	On or in compliance with the inventory.
Korea Existing Chemicals Inv. (KECI):	On or in compliance with the inventory.
Australia AICS:	On or in compliance with the inventory.
Philippines PICCS:	On or in compliance with the inventory.
New Zealand Inventory of Chemicals:	On or in compliance with the inventory.

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

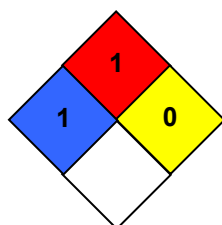
HMIS Hazard ID

Health	1
Flammability	1
Physical Hazards	0
PERSONAL PROTECTION	B

B - Safety Glasses & Gloves

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

NFPA Hazard ID



	Flammability
	Health
	Reactivity
	Special hazard.

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

Issue Date: 07/10/2018

Revision Date: No data available.

Version #: 6.0

SDS_US

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.