

## 1. Product and company identification

### Product identifier

Trade name: 616S5/616S6 – BetaSil

This safety data sheet pertains to the following products:

616S5=1: BetaSil

616S6=1: Refilling set BetaSil

### Recommended use and restrictions on use

General use: Component A for RTV - Silicone  
for orthopedic procedures and in scar compression therapy.  
Reserved for industrial and professional use.

### Initial supplier identifier

Company name: Otto Bock HealthCare Canada Ltd.

Street/POB-No.: 5470 Harvester Road

Postal Code, city: Burlington, ON L7L 5N5, CA  
Canada

WWW: [www.ottobock.ca](http://www.ottobock.ca)

E-mail: [info.canada@ottobock.com](mailto:info.canada@ottobock.com)

Telephone: (800) 665-3327

Telefax: (800) 463-3659

Department responsible for information:

Mark Agro, Telephone: (800) 665-3327 (9 am - 5 pm)

Additional information:

Corporate headquarters:  
Ottobock SE & Co. KGaA  
Max-Näder-Straße 15  
Duderstadt  
Germany

### Emergency phone number

COLLECT, Telephone: (613) 996-6666

Transport:

CONSULTANK Lutz Harder GmbH (Contract QUALI003)

Telephone: +49 (0)178-4337434 (from USA: 01149 178 4337434)

## 2. Hazards identification

### Emergency overview

Appearance: Form: pasty  
Color: characteristic  
Odor: characteristic  
Classification: Eye Irritation 2A.

Hazard symbols:



Signal word: **Warning**

Hazard statements: Causes serious eye irritation.

Precautionary statements: Wear protective gloves/protective clothing/eye protection/face protection.  
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
If eye irritation persists: Get medical advice/attention.

### Regulatory status

This material is considered hazardous by the U.S. OSHA Hazard Communication Standard (29 CFR 1910.1200) and WHMIS in Canada.

### Hazards not otherwise classified

see section 11: Toxicological information

## 3. Composition / Information on ingredients

Chemical characterisation: Paste

Relevant ingredients:

CAS No.	Designation	Concentration	Classification
CAS 68131-39-5	Alcohols, C12-15, ethoxylated	< 2.5 %	Eye Damage 1. Aquatic toxicity - acute 1.

Additional information: Contains Silicon dioxide.  
The maximum workplace exposure limits are, where necessary, listed in section 8.

## 4. First aid measures

In case of inhalation: Provide fresh air. Seek medical treatment in case of troubles.

Following skin contact: Remove mechanically with cloth or paper.  
afterwards: Thoroughly wash skin with soap and water.  
In case of skin irritation, consult a physician.

After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart.  
Remove contact lenses, if present and easy to do. Continue rinsing. Subsequently consult an ophthalmologist.

After swallowing: Never give anything by mouth to an unconscious person. Rinse mouth thoroughly with water. Seek medical treatment in case of troubles.

### Most important symptoms and effects, both acute and delayed

Causes serious eye irritation.

### Information to physician

Treat symptomatically.

## 5. Fire fighting measures

Flash point/flash point range:  
> 130 °C

Auto-ignition temperature: > 400 °C

Suitable extinguishing media:

Water spray jet, Foam, extinguishing powder, carbon dioxide

Extinguishing media which must not be used for safety reasons:

Full water jet

### Specific hazards arising from the chemical

Combustible. Potentially explosive vapor/air mixtures may form.

In case of fire may be liberated: silicon dioxide, carbon monoxide and carbon dioxide.

Special protective equipment and precautions for fire-fighters:

Wear a self-contained breathing apparatus and chemical protective clothing.

Additional information:

Cool endangered containers with water spray and, if possible, remove from danger zone. Use water spray jet to knock down vapors. Do not breathe fumes. Do not allow fire water to penetrate into surface or ground water.

## 6. Accidental release measures

Personal precautions:

Avoid contact with skin, eyes, and clothing. Provide fresh air. Wear appropriate protective equipment.

Environmental precautions:

Do not allow to penetrate into soil, waterbodies or drains.

Methods for clean-up:

Take up mechanically, placing in appropriate containers for disposal. Dispose of waste according to applicable legislation.

Additional information:

Special danger of slipping by leaking/spilling product.

## 7. Handling and storage

### Handling

Advices on safe handling:

Handle in accordance with good industrial hygiene and safety practice. Wear appropriate protective equipment. Avoid contact with skin, eyes, and clothing. Have eye wash bottle or eye rinse ready at work place.

Precautions against fire and explosion:

Take standard precautions to prevent fire.

### Storage

Requirements for storerooms and containers:

Keep container tightly closed. Keep only in the original container. Store at room temperature.

Hints on joint storage:

Keep away from food, drink and animal feedingstuffs.

## 8. Exposure controls / personal protection

### Exposure guidelines

Occupational exposure limit values:

CAS No.	Designation	Type	Limit value
14808-60-7	Silicon dioxide (Quartz (SiO <sub>2</sub> ))	Canada: OEL 8 hour	0.025 mg/m <sup>3</sup> (respirable fraction)
		Canada: OEL TWA	0.025 mg/m <sup>3</sup>
		Canada: OEL TWA	0.1 mg/m <sup>3</sup> (respirable fraction)
		Canada: VEMP	0.05 mg/m <sup>3</sup> (respirable fraction)
		USA: ACGIH: TWA	0.025 mg/m <sup>3</sup> (respirable fraction)
		USA: IDLH: TWA	25 mg/m <sup>3</sup> (respirable fraction, (cristobalite/tridymite)
		USA: IDLH: TWA	50 mg/m <sup>3</sup> (respirable fraction, quartz/tripoli)
		USA: NIOSH: TWA	0.05 mg/m <sup>3</sup> (respirable fraction)
		USA: OSHA: TWA	10 mg/m <sup>3</sup> / % SiO <sub>2</sub> + 2 (respirable fraction)
		USA: OSHA: TWA	250 mppcf/ % SiO <sub>2</sub> +5 (fine dust)
		USA: OSHA: TWA	30 mg/m <sup>3</sup> / % SiO <sub>2</sub> + 2 (inhalable fraction)

Additional information: silicon dioxide is embedded in the product and not available as respirable dusts.

### Engineering controls

Provide adequate ventilation.

See also information in chapter 7, section storage.

### Personal protection equipment (PPE)

Eye/face protection: Tightly sealed goggles according to OSHA Standard - 29 CFR: 1910.133 or ANSI Z87.1-2010.

Skin protection: Wear suitable protective clothing.  
Protective gloves according to OSHA Standard - 29 CFR: 1910.138.  
Glove material: nitrile rubber  
Breakthrough time: > 480 min.  
Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Respiratory protection: Respiratory protection is not necessary if room is well ventilated.

General hygiene considerations:

Avoid contact with eyes.  
When using do not eat, drink or smoke.  
Wash hands before breaks and after work.  
Have eye wash bottle or eye rinse ready at work place.

### Environmental exposure controls

Refer to 6.: Section "Environmental precautions".

## 9. Physical and chemical properties

### Information on basic physical and chemical properties

Appearance:	Form: pasty Color: characteristic
Odor:	characteristic
Odor threshold:	No data available
pH:	not applicable
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	> 300 °C
Flash point/flash point range:	> 130 °C
Evaporation rate:	No data available
Flammability:	No data available
Explosion limits:	No data available
Vapor pressure:	at 20 °C: ≤ 0.1 hPa
Vapor density:	≥ 1
Density:	at 25 °C: 1.2 - 1.7 g/cm <sup>3</sup>
Water solubility:	practically insoluble
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	> 400 °C
Thermal decomposition:	> 100 °C
Additional information:	No data available

## 10. Stability and reactivity

Reactivity:	Refer to subsection "Possibility of hazardous reactions".
Chemical stability:	Stable under recommended storage conditions.
Possibility of hazardous reactions:	No hazardous reaction when handled and stored according to provisions.
Conditions to avoid:	Excessive heating. Decomposition under formation of: formaldehyde
Incompatible materials:	Reacts with strong oxidizing agents. With exposure to moisture, product will release hydrogen.
Hazardous decomposition products:	Hydrogen, formaldehyde
Thermal decomposition:	> 100 °C

## 11. Toxicological information

### Toxicological tests

Acute toxicity:	LD50 Rat: > 5,000 mg/kg
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Toxicological effects:

- Acute toxicity (oral): Based on available data, the classification criteria are not met.
- Acute toxicity (dermal): Based on available data, the classification criteria are not met.
- Acute toxicity (inhalative): Lack of data.
- Skin corrosion/irritation: Based on available data, the classification criteria are not met.
- Serious eye damage/irritation: Eye Irritation 2A = Causes serious eye irritation.
- Sensitisation to the respiratory tract: Lack of data.
- Skin sensitisation: Based on available data, the classification criteria are not met.
- Not known to cause sensitization.
- Germ cell mutagenicity/Genotoxicity: Lack of data.
- Carcinogenicity: Lack of data.
- Reproductive toxicity: Lack of data.
- Effects on or via lactation: Lack of data.
- Specific target organ toxicity (single exposure): Lack of data.
- Specific target organ toxicity (repeated exposure): Lack of data.
- Aspiration hazard: Lack of data.

## 12. Ecological information

### Ecotoxicity

Aquatic toxicity: Fish toxicity:  
LC50: >200 mg/L/96h

### Mobility in soil

No data available

### Persistence and degradability

Further details: No data available

### Additional ecological information

General information: Do not allow to penetrate into soil, waterbodies or drains.

## 13. Disposal considerations

### Product

Recommendation: Incinerate according to applicable local, state and federal regulations.

### Package

Recommendation: Dispose of waste according to applicable legislation.  
Non-contaminated packages may be recycled.

## 14. Transport information

### UN number

ADR/RID, IMDG, IATA-DGR:  
not applicable

### UN proper shipping name

ADR/RID, IMDG, IATA-DGR:

Not restricted

### Transport hazard class(es)

ADR/RID, IMDG, IATA-DGR:

not applicable

### Packing group

ADR/RID, IMDG, IATA-DGR:

not applicable

### Environmental hazards

Marine pollutant:

no

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

No data available

### USA: Department of Transportation (DOT)

Proper shipping name:

Not restricted

### Canada: Transportation of Dangerous Goods (TDG)

Shipping name:

Not restricted

### Sea transport (IMDG)

Proper shipping name::

Not restricted

Marine pollutant:

no

### Air transport (IATA)

Proper shipping name::

Not restricted

### Further information

No dangerous good in sense of these transport regulations.

## 15. Regulatory information

### National regulations - Canada

Silicon dioxide (Quartz (SiO<sub>2</sub>)): DSL: listed

Alcohols, C12-15, ethoxylated: DSL: listed

### National regulations - U.S. Federal Regulations

Silicon dioxide (Quartz (SiO<sub>2</sub>)): TSCA Inventory: listed

Carcinogen Status:

IARC Rating: Group 1

OSHA Carcinogen: not listed

NTP Rating: listed

NIOSH Recommendations:

Occupational Health Guideline: 0553

Alcohols, C12-15, ethoxylated: TSCA Inventory: listed; UVCB

## National regulations - U.S. State Regulations

Silicon dioxide (Quartz (SiO<sub>2</sub>)): California Proposition 65: cancer

## 16. Other information

Text for labeling:

Contains < 2.5 % Alcohols, C12-15, ethoxylated.

Hazard rating systems:

NFPA Hazard Rating:

Health: 1 (Slight)

Fire: 1 (Slight)

Reactivity: 0 (Minimal)

HMIS Version III Rating:

Health: 1 (Slight)

Flammability: 1 (Slight)

Physical Hazard: 0 (Minimal)

Personal Protection: B



HEALTH	1
FLAMMABILITY	1
PHYSICAL HAZARD	0
B	

Abbreviations and acronyms:

ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways  
 ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road  
 Aquatic toxicity - acute: Hazardous to the aquatic environment - acute  
 AS/NZS: Australian Standards/New Zealand Standards  
 CAS: Chemical Abstracts Service  
 CFR: Code of Federal Regulations  
 CLP: Classification, Labelling and Packaging  
 DMEL: Derived minimal effect level  
 DNEL: Derived no-effect level  
 EC: European Community  
 EmS: Emergency Response Procedures for Ships Carrying Dangerous Goods  
 EN: European Standard  
 EQ: Excepted quantities  
 Eye Damage: Eye damage  
 Eye Irritation: Eye irritation  
 IATA: International Air Transport Association  
 IATA-DGR: International Air Transport Association – Dangerous Goods Regulations  
 IBC Code: International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk  
 IMDG Code: International Maritime Dangerous Goods Code  
 IMO: International Maritime Organization  
 LC50: Median lethal concentration  
 MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships  
 OSHA: Occupational Safety and Health Administration  
 PBT: Persistent, bioaccumulative and toxic  
 PNEC: Predicted no-effect concentration  
 RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail  
 TRGS: Technical Rules for Hazardous Substances  
 vPvB: Very persistent and very bioaccumulative  
 WHMIS: Workplace Hazardous Materials Information System

Reason of change:

Changes in section 8: Biological Limit Value

Changes in section 8: Occupational exposure limit values

Date of first version:

15/11/2018

### Department issuing data sheet

Contact person:

see section 1: Department responsible for information

The information in this data sheet has been established to our best knowledge and was up-to-date at time of revision. It does not represent a guarantee for the properties of the product described in terms of the legal warranty regulations.