

1 Identification

Product identifier

Trade name: 616S5/616S6 – BetaSil

Other means of identification

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

Email: 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 telephone number

COLLECT, Telephone: (613) 996-6666

2 Hazard identification

Classification

Eye Irritation 2A Causes serious eye irritation.

Information elements

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.

Other hazards known to the supplier with respect to the product

3 Composition/Information on ingredients

Mixture

Chemical name: Paste

Hazardous ingredients:

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

The actual concentration or concentration range is withheld as a trade secret.

Additional information: Contains Silicon dioxide.

The maximum workplace exposure limits are, where necessary, listed in section 8.

4 First-aid measures

Description of necessary first-aid measures

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

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

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

In case of 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.

Most important symptoms and effects, whether acute or delayed

Causes serious eye irritation.

Indication of immediate medical attention and special treatment needed, if necessary

Treat symptomatically.

5 Fire-fighting measures

Suitable and unsuitable extinguishing media

Suitable extinguishing media:

Water spray jet, Foam, extinguishing powder, carbon dioxide

Unsuitable extinguishing media:

Full water jet

Specific hazards arising from the product

Combustible. Potentially explosive vapour/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 vapours. Do not breathe fumes. Do not allow fire water to penetrate into surface or ground water.

6 Accidental release measures

Personal precautions, protective equipment and emergency procedures

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 and material for containment and cleaning 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

Precautions for safe 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.

Conditions for safe storage, including any incompatibilities

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

Control parameters

Occupational exposure limit values:

| CAS No. | Designation | Type | Limit value |
|------------|--|-----------------------------|---|
| 14808-60-7 | Silicon dioxide (Quartz (SiO ₂)) | Canada: Alberta, OEL 8 hour | 0.025 mg/m ³ (respirable fraction) |
| | | Canada: BC, OEL TWA | 0.025 mg/m ³ |
| | | Canada: Ontario, OEL TWA | 0.1 mg/m ³ (respirable fraction) |
| | | Canada: Québec, VEMP | 0.05 mg/m ³ (respirable fraction) |

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

Appropriate engineering controls

Provide adequate ventilation.

Individual protection measures, such as personal protective equipment

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

Hand protection: 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.

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

Body protection: Wear suitable protective clothing.

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

Physical state at 20 °C and 101.3 kPa

Form: pasty

Colour:

characteristic

Odour:

characteristic

Odour threshold:

No data available

Melting point and freezing point:

No data available

Boiling point or initial boiling point and boiling range:

> 300 °C

Flammability:

No data available

Lower and upper explosion limit or lower and upper flammability limit:

No data available

| | |
|--|---------------------------------------|
| Flash point/flash point range: | > 130 °C |
| Evaporation rate: | No data available |
| Auto-ignition temperature: | > 400 °C |
| Decomposition temperature: | > 100 °C |
| pH: | not applicable |
| Water solubility: | practically insoluble |
| Partition coefficient — n-octanol/water: | No data available |
| Vapour pressure: | at 20 °C: ≤ 0.1 hPa |
| Density and/or relative density | at 25 °C: 1.2 - 1.7 g/cm ³ |
| Vapour density: | ≥ 1 |
| Particle characteristics: | Not applicable |

Additional information

| | |
|-------------------------|-------------------|
| 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 |

11 Toxicological information

Information on the likely routes of exposure

No data available

Health hazard information

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.

Acute toxicity:

LD50 Rat: > 5,000 mg/kg

12 Ecological information

Ecotoxicity

Aquatic toxicity:

Fish toxicity:

LC50: >200 mg/L/96h

Persistence and degradability

Further details:

No data available

Bioaccumulative potential

Partition coefficient — n-octanol/water:

No data available

Mobility in soil

No data available

Other adverse effects

General information:

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

13 Disposal considerations

Waste treatment methods

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

TDG, IMDG, IATA-DGR: not applicable

UN proper shipping name

TDG, IMDG, IATA-DGR: Not restricted

Transport hazard class

TDG, IMDG, IATA-DGR: not applicable

Packing group

TDG, IMDG, IATA-DGR: not applicable

Environmental hazards

Marine pollutant: no

Special precautions in connection with transport or conveyance either within or outside the premises

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 (SiO₂)): DSL: listed

Alcohols, C12-15, ethoxylated: DSL: listed

Further regulations, limitations and legal requirements

No data available

16 Other information

Revision date: 17/12/2025

Date of first version: 15/11/2018

Reason of change: General revision: Safety Data Sheet according to Hazardous Products Regulations (HPR) 2022

General revision: Safety Data Sheet according to HCS 2024 (29 CFR 1910.1200)

Abbreviations and acronyms:

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
 DSL: Domestic Substances List
 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
 TDG: Transportation of Dangerous Goods Regulation in Canada
 TRGS: Technical Rules for Hazardous Substances
 vPvB: Very persistent and very bioaccumulative

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.