

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

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

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

Details of the supplier of the safety data sheet

Company name: Otto Bock Health Care
Street/POB-No.: 3820 W. Great Lakes Drive
Postal Code, city: Salt Lake City, UT 84120
USA

WWW: www.ottobockus.com

Telephone: +1 (801) 956-2400

Telefax: +1 (801) 956-2401

Department responsible for information:

Quality Department,
Telephone: +1 (801) 954-2304 (7 AM – 3 PM, Mountain Time),
Email: USRegulatory@ottobock.com

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

Emergency phone number

CHEMTREC, Telephone: +1 (800) 424-9300

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 - Category 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).

Hazards not otherwise classified

see section 11: Toxicological information

3. Composition / Information on ingredients

Chemical characterization: Paste

Relevant ingredients:

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

Causes serious eye irritation.

Information to physician

Treat symptomatically.

5. Fire fighting measures

Flash point/flash point range:

> 266 °F

Auto-ignition temperature: > 752 °F

Suitable extinguishing media:

Water spray jet, Foam, dry chemical 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.

Protective equipment and precautions for firefighters:

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 ₂))	USA: ACGIH: TWA	0.025 mg/m ³ (respirable fraction)
		USA: IDLH: TWA	25 mg/m ³ (respirable fraction, cristobalite/tridymite)
		USA: IDLH: TWA	50 mg/m ³ (respirable fraction, quartz/tripoli)
		USA: NIOSH: TWA	0.05 mg/m ³ (respirable fraction)
		USA: OSHA: TWA	10 mg/m ³ / % SiO ₂ + 2 (respirable fraction)
		USA: OSHA: TWA	250 mppcf/ % SiO ₂ +5 (fine dust)
		USA: OSHA: TWA	30 mg/m ³ / % SiO ₂ + 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:	> 572 °F
Flash point/flash point range:	> 266 °F
Evaporation rate:	No data available
Flammability:	No data available
Explosion limits:	No data available
Vapor pressure:	at 68 °F: ≤ 0.1 hPa
Vapor density:	≥ 1
Density:	at 77 °F: 1.2 - 1.7 g/cm ³
Water solubility:	practically insoluble
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	> 752 °F
Thermal decomposition:	> 212 °F
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:	> 212 °F

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 - Category 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

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 - U.S. Federal Regulations

Silicon dioxide (Quartz (SiO₂)): 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 (SiO₂)): California Proposition 65: cancer

National regulations - Canada

Silicon dioxide (Quartz (SiO₂)): DSL: listed

Alcohols, C12-15, ethoxylated: DSL: listed

National regulations - Great Britain

Hazchem-Code: -

16. Other information

Text for labeling:

Hazard rating systems:



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

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

Reason of change:

Changes in section 8: Biological Limit Value

Changes in section 8: Occupational exposure limit values

Date of first version:

11/15/2018

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.