

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name: 616S5/616S6 – BetaSil

This safety data sheet pertains to the following products:

616S5=1: BetaSil

616S6=1: Refilling set BetaSil

This safety data sheet pertains to the following products:

616S5=1 = BetaSil Kofferset, UFI: 9W10-A00A-H00Y-D4ST

616S6=1 = BetaSil Nachfüllset, UFI: 9W10-A00A-H00Y-D4ST

UFI: 9W10-A00A-H00Y-D4ST

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

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

1.3 Details of the supplier of the safety data sheet

Company name: Ottobock SE & Co. KGaA

Street/POB-No.: Max-Näder-Straße 15

Postal Code, city: 37115 Duderstadt

Germany

E-mail: export@ottobock.de

Telephone: +49 (0)5527 848-0

Telefax: +49 (0)5527 72330

Department responsible for information:

Arbeitssicherheit, Telephone: 05527-848-0, e-mail: Arbeitssicherheit@ottobock.de

Only available during office hours.

1.4 Emergency telephone number

GIZ-Nord, Germany, Telephone: +49 (0)551-19240

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to EC regulation 1272/2008 (CLP)

Eye Irrit. 2; H319 Causes serious eye irritation.

2.2 Label elements

Labelling (CLP)



Signal word: **Warning**

Hazard statements: H319 Causes serious eye irritation.

Precautionary statements: P280 Wear protective gloves/protective clothing/eye protection/face protection.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313 If eye irritation persists: Get medical advice/attention.

2.3 Other hazards

No risks worthy of mention.

Endocrine disrupting properties, Results of PBT and vPvB assessment:

No data available

SECTION 3: Composition/information on ingredients

3.1 Substances: not applicable

3.2 Mixtures

Chemical characterisation: Paste

Hazardous ingredients:

Identifiers	Designation Classification	Content
EC No. 500-195-7 CAS 68131-39-5	Alcohols, C12-15, ethoxylated Eye Dam. 1; H318. Aquatic Acute 1; H400.	< 2.5 %

Full text of H- and EUH-statements: see section 16.

Additional information: Contains Silicon dioxide.

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

SECTION 4: First aid measures

4.1 Description of 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.

4.2 Most important symptoms and effects, both acute and delayed

Causes serious eye irritation.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Water spray jet, Foam, extinguishing powder, carbon dioxide

Extinguishing media which must not be used for safety reasons:

Full water jet

5.2 Special hazards arising from the substance or mixture

Combustible. Potentially explosive vapour/air mixtures may form.

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

5.3 Advice for firefighters

Special protective equipment 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 vapours. Do not breathe fumes. Do not allow fire water to penetrate into surface or ground water.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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

6.2 Environmental precautions

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

6.3 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.

6.4 Reference to other sections

Refer additionally to section 8 and 13.

SECTION 7: Handling and storage

7.1 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.

7.2 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.

7.3 Specific end use(s)

No information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limit values:

CAS No.	Designation	Type	Limit value
14808-60-7	Silicon dioxide (Quartz (SiO ₂))	Europe: BOELV: TWA	0.1 mg/m ³ (respirable crystalline silica)

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

8.2 Exposure controls

Provide adequate ventilation.

Personal protection equipment

Occupational exposure controls

Respiratory protection:	Respiratory protection is not necessary if room is well ventilated.
Hand protection:	Protective gloves according to BS EN 374. 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 BS EN ISO 16321-1:2022.
Body protection:	Wear suitable protective clothing.
General protection and hygiene measures:	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 "6.2 Environmental precautions".

SECTION 9: Physical and chemical properties

9.1 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/freezing point:	No data available
Initial boiling point and boiling range:	> 300 °C
Flammability:	No data available
Upper/lower flammability or explosive limits:	No data available
Flash point/flash point range:	> 130 °C
Decomposition temperature:	> 100 °C
pH:	not applicable
Viscosity, kinematic:	No data available
Water solubility:	practically insoluble
Partition coefficient: n-octanol/water:	No data available
Vapour pressure:	at 20 °C: ≤ 0.1 hPa
Density:	at 25 °C: 1.2 - 1.7 g/cm ³
Vapour density:	≥ 1
Particle characteristics:	Not applicable

9.2 Other information

Explosive properties:	No data available
Oxidizing characteristics:	No data available
Auto-ignition temperature:	> 400 °C
Evaporation rate:	No data available
Additional information:	No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Refer to subsection "Possibility of hazardous reactions".

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No hazardous reaction when handled and stored according to provisions.

10.4 Conditions to avoid

Excessive heating. Decomposition under formation of: formaldehyde

10.5 Incompatible materials

Reacts with strong oxidizing agents.

With exposure to moisture, product will release hydrogen.

10.6 Hazardous decomposition products

Hydrogen, formaldehyde

Thermal decomposition: > 100 °C

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity:

LD50 Rat: > 5,000 mg/kg

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 Irrit. 2; H319 = 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.

11.2 Information on other hazards

Endocrine disrupting properties: No data available

Other information: No data available

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity:

Fish toxicity:

LC50: >200 mg/L/96h

12.2 Persistence and degradability

Further details:

No data available

12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water:

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Endocrine disrupting properties

No data available

12.7 Other adverse effects

General information:

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

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Waste key number:

07 02 17 = Waste containing silicones

Recommendation:

Incinerate according to applicable local, state and federal regulations.

Package

Waste key number:

15 01 02 = Plastic packaging

Recommendation:

Dispose of waste according to applicable legislation.

Non-contaminated packages may be recycled.

SECTION 14: Transport information

14.1 UN number or ID number

ADR/RID, ADN, IMDG, IATA-DGR:

not applicable

14.2 UN proper shipping name

ADR/RID, ADN, IMDG, IATA-DGR:

Not restricted

14.3 Transport hazard class(es)

ADR/RID, ADN, IMDG, IATA-DGR:

not applicable

14.4 Packing group

ADR/RID, ADN, IMDG, IATA-DGR:

not applicable

14.5 Environmental hazards

Dangerous for the environment: Substance/mixture is not environmentally hazardous

according to the criteria of the UN model regulations.

Marine pollutant - IMDG:

no

14.6 Special precautions for user

No dangerous good in sense of these transport regulations.

14.7 Maritime transport in bulk according to IMO instruments

No data available

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

National regulations - EC member states

Labelling of packaging with <= 125mL content



Signal word:

Warning

Hazard statements:

not applicable

Precautionary statements:

not applicable

Further regulations, limitations and legal requirements:

No data available

15.2 Chemical Safety Assessment

For this mixture a chemical safety assessment is not required.

SECTION 16: Other information

Wording of the H-phrases under paragraph 2 and 3:

H318 = Causes serious eye damage.

H319 = Causes serious eye irritation.

H400 = Very toxic to aquatic life.

Reason of change:

General revision

Date of first version:

15/11/2018

Department issuing data sheet: see section 1: Department responsible for information

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 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

EN: European Standard

EQ: Excepted quantities

EU: European Union

Eye Dam.: Eye damage

Eye Irrit.: 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

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

REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals

RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail

TRGS: Technical Rules for Hazardous Substances

vPvB: Very persistent and very bioaccumulative

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.