

1. <u>Product identification/preparation/company undertaking</u>	
Product details	
Product no.:	81211
Trade name:	BISICO Softbase cartridge
Trade number:	93810
Use or preparation:	Dental-Soft-Reliner
Manufacturer/supplier:	BISICO Bielefelder Dentsilicone GmbH & Co. KG Johanneswerkstraße 3 D-33611 Bielefeld
Emergency information:	Tel.: +49 521 8016800 Fax: +49 521 8016801
2. <u>Hazards identification</u>	
<u>Classification of the substance or mixture:</u>	
Classification according to Regulation (EC) 1272/2008:	void
Information concerning particular hazards for human and environment:	The product does not have to be labeled due to the calculation procedure of the „General classification guideline for preparations of the EU“ in the latest valid version.
Label elements:	-
Labeling according to Regulation (EC) 1272/2008:	-
Labeling according to EU guidelines:	Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body; are exempted from the provisions of Regulation (EC) No. 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.
<u>Other hazards:</u>	PBT: not applicable
Results of PBT and vPvB assessment:	vPvB: not applicable
3. <u>Composition/Information of Ingredients</u>	
<u>Chemical characterization:</u>	
Description:	mixture of polydimethyl polymethyl vinyl siloxane, polydimethyl polymethyl hydrogen siloxane and silica
Hazardous components:	none

<p>4. <u>First-aid measures</u></p> <p>General information: no special measures required</p> <p>after skin contact: wash with plenty of water and soap</p> <p>after eye contact: rinse with plenty of water and consult a doctor</p> <p>after swallowing: If symptoms persist consult a doctor</p>
<p>5. <u>Fire fighting measures</u></p> <p>Extinguishing media: CO₂, water</p> <p>Protective equipment: no special measures required</p>
<p>6. <u>Accidental release measures</u></p> <p>Personal precautions: not required</p> <p>Environmental precautions: no special measures required</p> <p>Methods for cleaning up: pick up mechanically</p> <p>Additional information: none</p>
<p>7. <u>Handling and storage</u></p> <p>Handling:</p> <p>Information for safe handling: For dental use only. No special measures required</p> <p>Recommendation for fire and explosion protection: No special measures required</p> <p>Storage:</p> <p>Requirements at storerooms and containers: No special measures required</p> <p>Requirements for storage with other products: not required</p> <p>Further information on storage conditions: none</p>
<p>8. <u>Exposure controls/personal protection</u></p> <p>Components with limits of values to be supervised at the workplace: The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace</p> <p>Additional information: The lists valid during the making were used as basis.</p> <p>Personal protective equipment: -</p>

General measures of protection and hygiene:	normal hygienic measures
Respiratory protection:	not required
Protection of hands:	not required
Eye protection:	not absolute required

9. Physical and chemical properties

Appearance:

Form:	Paste
Color:	A-Comp.: white, B-Comp.: gum-colored
Odor:	odorless

Value Unit Method

Information on change in the physical state

Melting point/melting range:	n.a.	°C
Boiling point/boiling range:	n.a.	°C
Flash point:	n.a.	°C
Autoignition temperature:	n.a.	
Danger of explosion:	none	
Density:	1,05 (20°C)	g/cm ³
Vapor pressure:	n.a.	mbar
Viscosity:	Paste	
pH:	neutral	
Solubility in/miscibility with:	Partially soluble in toluene, petrol ether	
Water:	insoluble	
Content of solvents:	none	
Organic solvents:	-	
Water:	-	
Content of solids:	n.a.	

10. Stability and reactivity

Conditions to avoid:	No decomposition if used according to specification
Hazardous decomposition products:	none under normal conditions of storage and use

11. <u>Toxicological information</u>	
Acute toxicity:	-
Primary irritation:	-
skin:	no irritating effect
eye:	no irritating effect
Additional toxicological information:	When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.
12. <u>Ecological information</u>	
General information:	Avoid transfer into environment
Classification of water endangerment:	WGK 1 (German regulation) slightly hazardous for water
13. <u>Disposal consideration</u>	
Product:	
Recommendation:	Small quantities can be disposed of with household waste. Use proper landfill disposal or incineration in accordance with local, state and federal regulations
Uncleaned packaging:	
Recommendation:	Disposal must be made according to official regulations.
14. <u>Transport information</u>	
Land transport ADR, RID:	-
Maritime transport: IMDG-Code:	-
Air transport ICAO-TI/IATA-DGR:	-
15. <u>Regulatory information</u>	
Classification according to EC-guidelines:	The product is a medical device according to EC-directive 93/42 EEC.
Chemical safety assessment:	A Chemical Safety Assessment has not been carried out.

<p>16. <u>Other information:</u></p> <p>Changes compared with the previous version: Adaptation according to 1907/2006/EG, Article 31</p> <p>The above information is based on our present day knowledge and relates solely to the safety requirements of the product. The data do not signify any warranty with regards to products properties. However users of the product should satisfy themselves that the information given is sufficient and correct for their specific circumstances of use.</p>	
<p>Preparation by:</p>	<p>S. Zimmermann Tel.: +49 521 8016800</p>