

SECTION 1. Product identification/preparation/company undertaking**1.1 Product identifier:**

Product no.: 81260
Trade name: BISICO Softbase Primer
Trade number: 13860

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

No further relevant information available.

Application of the substance / the mixture:

Dental-soft-reliner

1.3. Details of the supplier of the safety data sheet:

BISICO Bielefelder Dentalsilicone GmbH & Co. KG
Johanneswerkstraße 3
D-33611 Bielefeld
Tel.: +49 521 8016800
Fax: +49 521 8016801
Email: info@Bisico.de
responsible for the Safety Data Sheet: Sebastian Zimmermann

1.4. Emergency telephone number:

BISICO Bielefelder Dentalsilicone GmbH & Co. KG
Tel.: +49 521 8016800 (08:00-16:00 PM)
Fax: +49 521 8016801
S. Zimmermann

SECTION 2. Hazards identification**2.1 Classification of the substance or mixture:****2.1.1 Classification according to Regulation (EC) No 1272/2008:**

Flam. Liq. 2 H225 Highly flammable liquid and vapour.
Skin Irrit. 2 H319 Causes serious eye irritation
Skin Sens. 1 H317 May cause an allergic skin reaction.
STOT SE 3 H336 May cause drowsiness or dizziness

2.2 Label elements:

Labelling according to Regulation (EC) No 1272/2008: The product is classified and labelled according to the CLP regulation.

Hazard pictograms:

GHS02



GHS07

Signal word: Danger

Hazard statements:

H225 Highly flammable liquid and vapour.

H319 Causes serious eye irritation

H336 May cause drowsiness or dizziness

Precautionary statements:

P210 Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

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

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.

2.3 Other hazards:**Results of PBT and vPvB assessment:****PBT:** not applicable**vPvB:** not applicable**SECTION 3. Composition/Information of Ingredients****3.1 Substances:****3.2 Mixtures:****Chemical characterization:****Description:**

Solution of polyacrylate in ethylacetate

Hazardous components:

CAS-No. [141-78-6], EC-No. 2005-500-4

Ethylacetate GHS02, GHS07, H225, H319, H336

SECTION 4. First-aid measures**4.1 Description of first aid measures:****general information:**

no special measures required

after inhalation:

Supply fresh air

after skin contact:

wash with water and

after eye contact:

Rinse opened eye for several minutes under running water and consult a doctor

after swallowing:

Caution if victim vomits. Risk of aspiration. Keep airways free. Consult a physician. Subsequently administer: activated charcoal (20 – 40 g in 10% slurry). Laxative: Sodium sulfate (1 tablespoon/ ¼ l water).

4.2 Most important symptoms and effects, both acute and delayed:

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed:

No further relevant information available.

SECTION 5. Fire fighting measures**5.1 Extinguishing media:**

Suitable extinguishing agents: CO₂, powder, water spray. Use extinguishing method and media suitable to surrounding fire

5.2 Special hazards arising from the substance or mixture: No further relevant information available.

5.3 Advice for firefighters:**Protective equipment:**

Wear self-contained respiratory protective device.

SECTION 6. Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures:**

Do not inhale vapours/aerosols. Avoid substance contact. Ensure supply of fresh air in enclosed rooms

6.2 Environmental precautions:

Do not allow to enter drains/surface water/ ground-water.

6.3 Methods for cleaning up:

Absorb with liquid binding material. Clean up affected area.

6.4 Reference to other sections: See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7. Handling and storage**Handling:**

This product should only be supplied or handled to dentists or dental technicians or upon their instructions.

7.1 Precautions for safe handling:

Observe normal care for working with chemicals.

Information about fire - and explosion protection:

No special measures required

7.2 Conditions for safe storage, including any incompatibilities:**Requirements to be met by storerooms and receptacles:**

Store only in the original containers

Further information about storage conditions:

Store in well ventilated place at 15 °C to 25 °C, protected from light. Store away from food stuffs. Store tightly closed. Keep away from heat and sources of ignition.

7.3 Specific end use(s):

No further relevant information available.

SECTION 8. Exposure controls/personal protection**8.1. Control parameters:****Ingredients with limit values that require monitoring at the workplace:**

CAS-No.	name	art	value	unit
[141-78-6]	Ethylacetate	TRGS900	400	ml/m ³
		or	1500	mg/m ³

Additional information: The lists valid during the making were used as basis.

8.2 Exposure controls:**Personal protective equipment****General protective and hygienic measures:**

The usual precautionary measures are to be adhered to when handling chemicals.
Keep away from foodstuffs and beverages. Avoid contact with eyes or skin

Hand protection:

Protective gloves.

Due to missing tests no recommendation to the glove material can be given for the product.

Eye protection: safety glasses

Respiratory protection: Required, when aerosols are generated

SECTION 9. Physical and chemical properties**9.1. Information on basic physical and chemical properties:****Appearance**

Form:	liquid		
Color:	slightly yellow		
Odor:	sweetish		
	<u>Value</u>	<u>Unit</u>	<u>Method</u>

Safety relevant basic data

Melting point/melting range:	n.a.		
Boiling point/boiling range:	approx. 77		°C
Flash point:	-4		°C
Ignition temperature:	No information available		
Danger of explosion:			
Lower limit of explosion	2.1 Vol%	Kühn-	
Upper limit of explosion	11.5 Vol%	Birett	
Density:	ca. 0,9 (20°C)	g/cm ³	
Vapor pressure:	n.d.		
Solubility in/miscibility with:			
Water:	soluble		
Content of solvents:			
Organic solvents:	ethylacetate		

9.2 Other information No further relevant information available.

SECTION 10. Stability and reactivity**10.1. Reactivity:****10.2. Chemical stability:****10.3 Possibility of hazardous reactions:** no information available**10.4 Conditions to avoid:**

Heat, direct sunlight and radical starters. The product is stable by proper use. Avoid contact with alkali metals, hydrides, strong oxidizing agents, radical initiators.

10.5 Incompatible materials:**10.6 Hazardous decomposition products:** No information available.**SECTION 11. Toxicological information****11.1. Information on toxicological effects:****Acute toxicity:**

LD ₅₀ (oral, rat)	5600 mg/kg
LD ₅₀ (dermal, rabbit)	>18000 mg/kg
LD ₅₀ (inhal., rat)	5,86 mg/l (8h)

Primary irritant effect:**Skin corrosion/irritation:** repeated exposure may cause skin dryness or cracking**Serious eye damage/irritation:** strong irritating effect**Inhalation and swallowing:** irritation of mucous membranes, loss of appetite, headache, drowsiness**Additional toxicological information:**

Allergic reactions to acrylates after long-term exposure are possible. When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

SECTION 12. Ecological information**12.1 Toxicity:****Acquatic toxicity:** No further relevant information available.**12.2 Persistence and degradability:** No further relevant information available.**Behaviour in environmental systems:****12.3 Bioaccumulative potential:** No further relevant information available.**12.4 Mobility in soil:** No further relevant information available.

Additional ecological information:

General notes: Do not flush into surface water or sanitary sewer system

12.5 Results of PBT and vPvB assessment: PBT: Not applicable.
vPvB: Not applicable.

12.6 Other adverse effects: No further relevant information available.

SECTION 13. Disposal consideration**13.1. Waste treatment methods:****Product:**

Recommendation: 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

SECTION 14. Transport information**14.1 UN-Number**

ADR, IMDG, IATA: UN1173

14.2 UN proper shipping name**ADR:**

ETHYLACETAT

IMDG:

ETHYLACETAT

IATA:

ETHYLACETATE

14.3 Transport hazard class(es)**ADR:**

UN 1173 ETHYLACETAT, 3, II

IMDG, IATA:

UN 1173 ETHYLACETAT, 3, II

Air transport ICAO-TI and IATA-DGR:

UN 1173 ETHYLACETATE, 3, II

14.4 Packing group**ADR, IMDG, IATA:**

II

14.5 Environmental hazards:

Marine pollutant: No

14.6 Special precautions for user:**14.7 Transport in bulk according to Annex II of Marpol and the IBC Code:**

-

The transport regulations are cited according to international regulations and in the form applicable in Germany. Possible national deviations in other countries are not considered.

SECTION 15. Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture:****Classification according to EC-guidelines:**

The product is a medical device according to EC-directive 93/42 EEC

15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16. Other information:

Changes compared with the previous version: Adaptation according to 1907/2006/EG, Article 31

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.

Preparation by:

S. Zimmermann

Tel.: +49 521 8016800

<p>1. <u>Product identification/preparation/company undertaking</u></p> <p>Product details</p> <p>Product no.: 81240</p> <p>Trade name: BISICO Softbase Glanzlack</p> <p>Trade number: 13850</p> <p>Use or preparation: Dental-Soft-Reliner</p> <p>Manufacturer/supplier: BISICO Bielefelder Dentalsilicone GmbH & Co. KG Johanneswerkstraße 3 D-33611 Bielefeld</p> <p>Emergency information: Tel.: +49 521 8016800 Fax: +49 521 8016801</p>	
<p>2. <u>Hazards identification</u></p> <p><u>Classification of the substance or mixture:</u></p> <p>Classification according to Regulation (EC) 1272/2008: void</p> <p>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.</p> <p>Label elements: -</p> <p>Labeling according to Regulation (EC) 1272/2008: void</p> <p>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.</p> <p><u>Other hazards:</u> PBT: not applicable</p> <p>Results of PBT and vPvB assessment: vPvB: not applicable</p>	
<p>3. <u>Composition/Information of Ingredients</u></p> <p><u>Chemical characterization:</u></p> <p>Description: mixture of polydimethyl polymethyl vinyl siloxane, polydimethyl polymethyl hydrogen siloxane and silica</p> <p>Hazardous components: none</p>	

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

Respiratory protection:	not required
Protection of hands:	not required
Eye protection:	not absolute required

9. Physical and chemical properties

Appearance:

Form:	Paste
Color:	clear
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: ca. 1,0 (20°C) g/cm³

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. Toxicological information

Acute toxicity:

Primary irritation:

	<p>skin: no irritating effect</p> <p>eye: no irritating effect</p> <p>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.</p>	
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.
16.	<u>Other information:</u>	
	Changes compared with the previous version:	Adaptation according to 1907/2006/EG, Article 31
<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>		
Preparation by:		S. Zimmermann Tel.: +49 521 8016800

<p>1. <u>Product identification/preparation/company undertaking</u></p> <p>Product details</p> <p>Product no.: 81211</p> <p>Trade name: BISICO Softbase cartridge</p> <p>Trade number: 93810</p> <p>Use or preparation: Dental-Soft-Reliner</p> <p>Manufacturer/supplier: BISICO Bielefelder Dentsilicone GmbH & Co. KG Johanneswerkstraße 3 D-33611 Bielefeld</p> <p>Emergency information: Tel.: +49 521 8016800 Fax: +49 521 8016801</p>	
<p>2. <u>Hazards identification</u></p> <p><u>Classification of the substance or mixture:</u></p> <p>Classification according to Regulation (EC) 1272/2008: void</p> <p>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.</p> <p>Label elements: -</p> <p>Labeling according to Regulation (EC) 1272/2008: -</p> <p>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.</p> <p><u>Other hazards:</u> PBT: not applicable</p> <p>Results of PBT and vPvB assessment: vPvB: not applicable</p>	
<p>3. <u>Composition/Information of Ingredients</u></p> <p><u>Chemical characterization:</u></p> <p>Description: mixture of polydimethyl polymethyl vinyl siloxane, polydimethyl polymethyl hydrogen siloxane and silica</p> <p>Hazardous components: none</p>	

<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>