Safety Information Sheet for Medical Devices
following 1907/2006/EG, Article 31

Date of issue: 17.06.2024 Version: 1
Printing date: 17.06.2024

This product is a medical device as defined in Directive 93/42/EEC on medical devices (MDD) respectively Regulation (EU) 2017/745 (MDR), which is invasive or used in direct physical contact with the human body. For this product a safety data sheet is not legally required. The provision of this document is on a voluntary basis.

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

1.1 Product identifier
Trade name:
Softbase Varnish

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

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

1.3 Details of the supplier of the safety information sheet

Manufacturer/supplier:
Bisico GmbH
Johanneswerkstraße 3
33611 Bielefeld, Germany
info@bisico.de

Distributor:
Bisico Bielefelder Dentalsilicone GmbH & Co.KG
Johanneswerkstraße 3
33611 Bielefeld, Germany
info@bisico.de

1.4 Emergency telephone number
+49 521 80168-00

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Medical devices as defined in Directive 93/42/EEC on medical devices (MDD) respectively Regulation (EU) 2017/245, which are invasive or used in direct physical contact with the human body are exempt from labeling requirements of Regulation (EC) No. 1272/2008 (CLP/GHS). Although not required, classification and labeling are indicated as follows:

Classification:
None.

2.2 Label elements
CLP Regulation (EC) No. 1272/2008
None.

2.3 Other hazards
Results of PBT and vPvB assessment:
PBT: not applicable.
vPvB: not applicable.

SECTION 3: Composition/information on ingredients

3.1 Substances
Not applicable.

3.2 Mixtures
Chemical characterization (description):
Mixture of polydimethyl polymethyl vinyl siloxane, polydimethyl polymethyl hydrogen siloxane and silica.

Hazardous components:
None.

SECTION 4: First aid measures

4.1 Description of first aid measures
General information:
Seek medical advice, if symptoms occur, which can be caused by the product.

after skin contact:
Wash with plenty of water and soap.

after inhalation:
Fresh air.

after eye contact:
Rinse with plenty of water and consult a doctor.

after swallowing:
If symptoms persist consult a doctor.

SECTION 5: Firefighting measures

5.1 Extinguishing media
Extinguishing media:
CO_2, extinguishing 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.

Protective equipment:
Wear self-contained respiratory protective equipment.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Personal precautions:
Not required.

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

6.3 Methods and material for containment and cleaning up
Pick up mechanically. Clean up affected area.

6.4 Reference to other sections
See Section 7: Handling and storage
See Section 8: Exposure controls/personal protection
See Section 13: Disposal considerations

SECTION 7: Handling and storage

7.1 Precautions for safe handling
Handling:
This product should only be supplied or handled to dentists or dental technicians or upon their instructions.

Information 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
Storage:
Store at a dry place. Store tightly closed. Storage temperature < 25°C.

Requirements at storerooms and containers:
Store only in the original containers.

Information about storage in one common storage facility:
Store away from food stuffs.

Further information on storage conditions:
None.

Storage class:
-

7.3 Specific end use(s)
No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters
Additional information on the design of technical systems:
-

Components with limits of values to be supervised at the workplace:
The product contains no relevant quantities of components with limits of values to be supervised at the workplace.

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

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

Normal 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.

Respiratory protection:
Required, when aerosols are generated.

Hand protection:
Protective gloves. Due to missing tests no recommendation to the glove material can be given for the product.

Eye protection:
Safety glasses.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance:

Form:	paste
Color:	different
Odor:	odorless

Change in condition:

Melting point/melting range:	not applicable
Boiling point/boiling range:	not applicable
Flash point:	not applicable
Ignition temperature:	not applicable
Danger of explosion:	none
Density:	~ 1.0 (20°C) g/cm^3
Vapor pressure:	not applicable
pH:	neutral
Solubility in/miscibility with:	partially soluble in toluene, petrol ether
Water:	insoluble
Content of solvents:	none
Organic solvents:	none

SECTION 10: Stability and reactivity

10.1 Reactivity
Expected to be non-reactive under normal conditions of use.

10.2 Chemical stability
The product is stable by proper use and storage.

10.4 Conditions to avoid
Heat, sunlight.

10.6 Hazardous decomposition products
No information available.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
Acute toxicity:
No data available.

Primary irritation:
Skin: no irritating effect.

Eye: no irritating effect.

Sensitization: no sensitizing effect known.

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.

SECTION 12: Ecological information

General information:
Avoid transfer into environment.

Classification of water endangerment:
WGK=1 (slightly polluting substance).

SECTION 13: Disposal considerations

13.1 Waste treatment methods
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.

SECTION 14: Transport information

Land transport ADR/RID and GGVSE (Germany):
No subject to transport regulations.

Sea transport IMDG Code:
No subject to transport regulations.

Air transport ICAO-TI and IATA-DGR:
No subject to transport regulations.

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
National regulations:
Water endangerment WGK=1 (slightly polluting substance).

15.2 Chemical safety assessment
A chemical safety assessment has not been carried out.

SECTION 16: Other information

For invasive medical devices or medical devices in direct contact with the human body, the Medical Device Regulation does not require a safety data sheet. The safe use of the product is indicated in the instructions for use and/or the labeling.

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.
Users of the product should satisfy themselves that the information given is sufficient and correct for their specific circumstances of use.

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following 1907/2006/EG, Article 31

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

1.1 Product identifier
Trade name:
Softbase Primer

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

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

1.3 Details of the supplier of the safety information sheet

Manufacturer/supplier:
Bisico GmbH
Johanneswerkstraße 3
33611 Bielefeld, Germany
info@bisico.de

Distributor:
Bisico Bielefelder Dentalsilicone GmbH & Co.KG
Johanneswerkstraße 3
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+49 521 80168-00

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Medical devices as defined in Directive 93/42/EEC on medical devices (MDD) respectively Regulation (EU) 2017/245, which are invasive or used in direct physical contact with the human body are exempt from labeling requirements of Regulation (EC) No. 1272/2008 (CLP/GHS). Although not required, classification and labeling are indicated as follows:

Classification:
Flammable liquid, Category 2, H225 Highly flammable liquid and vapour.
Eye irritation, Category 2; H319 Causes serious eye irritation.
Specific target organ toxicity – single exposure (STOT SE), Category 3; H H336 May cause drowsiness or dizziness.

2.2 Label elements
CLP Regulation (EC) No. 1272/2008

Signal word:
Danger.

Hazard pictograms:


GHS02


GHS07

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/opem 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.

2.3 Other hazards
Results of PBT and vPvB assessment:

PBT:	not applicable.
vPvB:	not applicable.

SECTION 3: Composition/information on ingredients

3.1 Substances
Not applicable.

3.2 Mixtures
Chemical characterization (description):
Solution of polyacrylate in ethylacetate.

Hazardous components:

CAS-No. 141-78-6	Ethylacetate	GHS02, GHS07, H225, H319, H336

SECTION 4: First aid measures

4.1 Description of first aid measures
General information:
Seek medical advice, if symptoms occur, which can be caused by the product.

after skin contact:
Wash with plenty of water and soap.

after inhalation:
Fresh air.

after eye contact:
Rinse with plenty of water and consult a doctor.

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

SECTION 5: Firefighting measures

5.1 Extinguishing media
Extinguishing media:
CO_2, extinguishing powder, water spray. Use extinguishing method and media suitable to surrounding fire.

5.2 Special hazards arising from the substance or mixture
Flammable material, vapors are heavier than air. In the event of a fire, the formation of dangerous flammable gases and vapors is possible.

Protective equipment:
Wear self-contained respiratory protective equipment.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Personal precautions:
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 and material for containment and cleaning up
Absorb with liquid binding material. Clean up affected area.

6.4 Reference to other sections
See Section 7: Handling and storage
See Section 8: Exposure controls/personal protection
See Section 13: Disposal considerations

SECTION 7: Handling and storage

7.1 Precautions for safe handling
Handling:
This product should only be supplied or handled to dentists or dental technicians or upon their instructions.

Information 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
Storage:
Store at a dry place. Store tightly closed. Storage temperature < 25°C. Keep away from sources of ignition and heat.

Requirements at storerooms and containers:
Store only in the original containers. Store tightly closed. Keep away from heat and sources of ignition.

Information about storage in one common storage facility:
Store away from food stuffs.

Further information on storage conditions:
None.

Storage class:
-

7.3 Specific end use(s)
No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters
Additional information on the design of technical systems:
-

Components with limits of values to be supervised at the workplace:

CAS-No.	name	art		value	unit
141-78-6	Ethylacetate	TRGS 900		400	ml/m3
			Or	1500	mg/m3

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

8.2 Exposure controls
Personal protective equipment:
General protective and hygienic measures:
Personal protective equipment must be selected specifically for the workplace depending on the concentration and quantity of hazardous substances. Normal 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.

Respiratory protection:
Required, when aerosols are generated.

Hand protection:
Protective gloves. Due to missing tests no recommendation to the glove material can be given for the product.

Eye protection:
Safety glasses.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties
Appearance:

Form:	liquid
Color:	slightly yellow
Odor:	sweetish

Change in condition:		
Melting point/melting range:	not determined	
Boiling point/boiling range:	~ 77 °C	
Flash point:	- 4 °C DIN 51755	
Ignition temperature:	no information available	
Danger of explosion:	lower limit of explosion:	2.1 Vol%
	upper limit of explosion:	11.5 Vol%
Density:	~ 0.90 (20°C) g/cm^3	
Vapor pressure:	not determined	
Solubility in/miscibility with:	soluble in most organic solvents	
Water:	soluble	
Content of solvents:		
Organic solvents:	ethylacetate	
Water:	none	

SECTION 10: Stability and reactivity

10.1 Reactivity
Expected to be non-reactive under normal conditions of use.

10.2 Chemical stability
The product is stable by proper use and storage.

10.4 Conditions to avoid
Heat, sunlight, water with air, strong oxidizing agents, radical initiators.

10.6 Hazardous decomposition products
No information available.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
Acute toxicity:

LD50 (oral, rat)	5600 mg/kg
LD50 (dermal, rabbit)	>18000 mg/kg
LD50 (inhal., rat)	5,86 mg/l (8h).

Primary irritation:

Skin:	repeated exposure may cause skin dryness or cracking.
Eye:	strong irritating effect.
Inhalation and swallowing:	irritation of mucous membranes, loss of appetite, headache, drowsiness.

Additional toxicological information:
Allergic reactions to the product 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

General information:
Avoid transfer into environment.

Classification of water endangerment:
WGK=1 (slightly polluting substance).

SECTION 13: Disposal considerations

13.1 Waste treatment methods
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

Land transport ADR/RID and GGVSE (Germany):
UN 1173 ETHYLACETAT, 3, II.

Sea transport IMDG Code:
UN 1173 ETHYLACETATE, 3, II; EmS: F-E S-D.

Air transport ICAO-TI and IATA-DGR:
UN 1173 ETHYLACETATE, 3, II.

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
National regulations:
Water endangerment WGK=1 (slightly polluting substance).

15.2 Chemical safety assessment
A chemical safety assessment has not been carried out.

SECTION 16: Other information

For invasive medical devices or medical devices in direct contact with the human body, the Medical Device Regulation does not require a safety data sheet. The safe use of the product is indicated in the instructions for use and/or the labeling.

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.
Users of the product should satisfy themselves that the information given is sufficient and correct for their specific circumstances of use.

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

1.1 Product identifier
Trade name:
Softbase

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

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

1.3 Details of the supplier of the safety information sheet

Manufacturer/supplier:
Bisico GmbH
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1.4 Emergency telephone number
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SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Medical devices as defined in Directive 93/42/EEC on medical devices (MDD) respectively Regulation (EU) 2017/245, which are invasive or used in direct physical contact with the human body are exempt from labeling requirements of Regulation (EC) No. 1272/2008 (CLP/GHS). Although not required, classification and labeling are indicated as follows:

Classification:
None.

2.2 Label elements
CLP Regulation (EC) No. 1272/2008
None.

2.3 Other hazards
Results of PBT and vPvB assessment:
PBT: not applicable.
vPvB: not applicable.

SECTION 3: Composition/information on ingredients

3.1 Substances
Not applicable.

3.2 Mixtures
Chemical characterization (description):
Mixture of polydimethyl polymethyl vinyl siloxane, polydimethyl polymethyl hydrogen siloxane and silica.

Hazardous components:
None.

SECTION 4: First aid measures

4.1 Description of first aid measures
General information:
Seek medical advice, if symptoms occur, which can be caused by the product.

after skin contact:
Wash with plenty of water and soap.

after inhalation:
Fresh air.

after eye contact:
Rinse with plenty of water and consult a doctor.

after swallowing:
If symptoms persist consult a doctor.

SECTION 5: Firefighting measures

5.1 Extinguishing media
Extinguishing media:
CO_2, extinguishing 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.

Protective equipment:
Wear self-contained respiratory protective equipment.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Personal precautions:
Not required.

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

6.3 Methods and material for containment and cleaning up
Pick up mechanically. Clean up affected area.

6.4 Reference to other sections
See Section 7: Handling and storage
See Section 8: Exposure controls/personal protection
See Section 13: Disposal considerations

SECTION 7: Handling and storage

7.1 Precautions for safe handling
Handling:
This product should only be supplied or handled to dentists or dental technicians or upon their instructions.

Information 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
Storage:
Store at a dry place. Store tightly closed. Storage temperature < 25°C.

Requirements at storerooms and containers:
Store only in the original containers.

Information about storage in one common storage facility:
Store away from food stuffs.

Further information on storage conditions:
None.

Storage class:
-

7.3 Specific end use(s)
No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters
Additional information on the design of technical systems:
-

Components with limits of values to be supervised at the workplace:
The product contains no relevant quantities of components with limits of values to be supervised at the workplace.

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

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

Normal 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.

Respiratory protection:
Required, when aerosols are generated.

Hand protection:
Protective gloves. Due to missing tests no recommendation to the glove material can be given for the product.

Eye protection:
Safety glasses.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance:

Form:	paste
Color:	different
Odor:	odorless

Change in condition:

Melting point/melting range:	not applicable
Boiling point/boiling range:	not applicable
Flash point:	not applicable
Ignition temperature:	not applicable
Danger of explosion:	none
Density:	1.05 (20°C) g/cm^3
Vapor pressure:	not applicable
pH:	neutral
Solubility in/miscibility with:	partially soluble in toluene, petrol ether
Water:	insoluble
Content of solvents:	none
Organic solvents:	none

SECTION 10: Stability and reactivity

10.1 Reactivity
Expected to be non-reactive under normal conditions of use.

10.2 Chemical stability
The product is stable by proper use and storage.

10.4 Conditions to avoid
Heat, sunlight.

10.6 Hazardous decomposition products
No information available.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
Acute toxicity:
No data available.

Primary irritation:
Skin: no irritating effect.

Eye: no irritating effect.

Sensitization: no sensitizing effect known.

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.

SECTION 12: Ecological information

General information:
Avoid transfer into environment.

Classification of water endangerment:
WGK=1 (slightly polluting substance).

SECTION 13: Disposal considerations

13.1 Waste treatment methods
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.

SECTION 14: Transport information

Land transport ADR/RID and GGVSE (Germany):
No subject to transport regulations.

Sea transport IMDG Code:
No subject to transport regulations.

Air transport ICAO-TI and IATA-DGR:
No subject to transport regulations.

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
National regulations:
Water endangerment WGK=1 (slightly polluting substance).

15.2 Chemical safety assessment
A chemical safety assessment has not been carried out.

SECTION 16: Other information

For invasive medical devices or medical devices in direct contact with the human body, the Medical Device Regulation does not require a safety data sheet. The safe use of the product is indicated in the instructions for use and/or the labeling.

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.
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