

Safety Data Sheet

according to 1907/2006/EC, Article 31

Printing date 26.06.2013

Revision: 01.06.2013

1 Identification of the substance/preparation and of the company/undertaking

- **Product details**
- **Trade name:** Bifix SE Base
- **Application of the substance / the preparation** Dental luting cement
- **Manufacturer/Supplier:**
VOCO GmbH
Anton-Flettner-Str. 1-3
D-27472 Cuxhaven
- **Further information obtainable from:** Scientific department tel. +49 (0)4721-719-0
- **Information in case of emergency:** Giftinformationszentrum Mainz +49 (0)6131-19240

2 Hazards identification

- **Hazard description:** Not applicable.
- **Information concerning particular hazards for human and environment:**
The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
- **Classification system:**
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

3 Composition/information on ingredients

- **Chemical characterization**
- **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 72869-86-4 EINECS: 276-957-5	Urethanedimethacrylate	R 52/53	5-10%
CAS: 1830-78-0 EINECS: 217-388-4	Glycerindimethacrylate	Xi; R 36/37/38	5-10%
	Catalyst	Xn, Xi; R 22-41	≤ 2.5%
	Initiator	Xn; R 22	≤ 2.5%

4 First aid measures

- **General information:** No special measures required.
- **After inhalation:** Seek medical treatment in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.

5 Fire-fighting measures

- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Person-related safety precautions:** Not required.
- **Measures for environmental protection:** Do not allow to enter sewers/ surface or ground water.
- **Measures for cleaning/collecting:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

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· **Additional information:** *No dangerous substances are released.*

7 Handling and storage

- **Handling:**
- **Information for safe handling:**
For dental use only.
No special measures required.
- **Information about fire - and explosion protection:** *No special measures required.*
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** *See storage instructions on package*
- **Information about storage in one common storage facility:** *Not required.*
- **Further information about storage conditions:** *None.*

8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** *No further data; see item 7.*
- **Ingredients with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** *The lists valid during the making were used as basis.*
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** *Not required.*
- **Protection of hands:** *Not required.*
- **Material of gloves:** *Not applicable.*
- **Penetration time of glove material:** *Not applicable.*
- **Eye protection:** *Safety glasses*

9 Physical and chemical properties

· General Information

Form:	<i>Pasty</i>
Colour:	<i>According to product specification</i>
Odour:	<i>Characteristic</i>

· Change in condition

Melting point/Melting range: *Undetermined.*
Boiling point/Boiling range: *Undetermined.*

· **Flash point:** *Not applicable.*

· **Self-igniting:** *Product is not selfigniting.*

· **Danger of explosion:** *Product does not present an explosion hazard.*

· **Density:** *Not determined.*

· **Solubility in / Miscibility with water:** *Not miscible or difficult to mix.*

10 Stability and reactivity

- **Thermal decomposition / conditions to be avoided:** *No decomposition if used according to specifications.*

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- **Dangerous reactions** *No dangerous reactions known.*
- **Dangerous decomposition products:** *No dangerous decomposition products known.*

11 Toxicological information

- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** *No irritant effect.*
- **on the eye:** *No irritating effect.*
- **Sensitization:** *No sensitizing effects known.*
- **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.
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 Ecological information

- **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

13 Disposal considerations

- **Product:**
- **Recommendation** *Smaller quantities can be disposed of with household waste.*
- **Uncleaned packaging:**
- **Recommendation:** *Disposal must be made according to official regulations.*

14 Transport information

- **Land transport ADR/RID (cross-border)**
- **ADR/RID class:** -
- **Maritime transport IMDG:**
- **IMDG Class:** -
- **Marine pollutant:** *No*
- **Air transport ICAO-TI and IATA-DGR:**
- **ICAO/IATA Class:** -

15 Regulatory information

- **Labelling according to EU guidelines:**
Observe the general safety regulations when handling chemicals.
The product is not subject to identification regulations under EU Directives and the Ordinance on Hazardous Materials (German GefStoffV).

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16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Department issuing MSDS:** Scientific department
- **Contact:** Tel.: +49 (0)4721-719-0

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- **Trade name:** Bifix SE catalyst
- **Application of the substance / the preparation** Dental luting cement
- **Manufacturer/Supplier:**
VOCO GmbH
Anton-Flettner-Str. 1-3
D-27472 Cuxhaven
- **Further information obtainable from:** Scientific department tel. +49 (0)4721-719-0
- **Information in case of emergency:** Poison Control Center Mainz +49 (0)6131-19240

2 Hazards identification

- **Hazard description:**
Xi Irritant
- **Information concerning particular hazards for human and environment:**
The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
R 36/38 Irritating to eyes and skin.
R 43 May cause sensitisation by skin contact.
- **Classification system:**
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.
- **Additional information:** *Use only for intended scope of application*

3 Composition/information on ingredients

- **Chemical characterization**
- **Description:** *Mixture of substances listed below with nonhazardous additions.*

· **Dangerous components:**

CAS: 1830-78-0 EINECS: 217-388-4	Glycerindimethacrylate	Xi; R 36/37/38	5-10%
	Acidic adhesive monomer	C; R 34-36/38	5-10%
CAS: 72869-86-4 EINECS: 276-957-5	Urethanedimethacrylate	R 52/53	5-10%
CAS: 1565-94-2	BIS-GMA	Xi; R 36/38	5-10%
CAS: 27813-02-1 EINECS: 248-666-3	Hydroxypropylmethacrylate	Xi; R 36/38-43	≤ 2.5%
	benzoyl peroxyde	Xi, E, O; R 3-7-36-43	≤ 2.5%

4 First aid measures

- **After inhalation:**
Seek medical treatment in case of complaints.
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:** *Immediately wash with water and soap and rinse thoroughly.*
- **After eye contact:**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing:** *If symptoms persist consult doctor.*

5 Fire-fighting measures

- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

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· **Protective equipment:** No special measures required.

6 Accidental release measures

- **Person-related safety precautions:** Not required.
- **Measures for environmental protection:** Do not allow to enter sewers/ surface or ground water.
- **Measures for cleaning/collecting:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

7 Handling and storage

- **Handling:**
- **Information for safe handling:** For dental use only.
- **Information about fire - and explosion protection:** No special measures required.
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** See storage instructions on package
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Keep container tightly sealed.

8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Ingredients with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
- **Protection of hands:**



Protective gloves

- **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** Safety glasses

9 Physical and chemical properties

General Information

Form:	Pasty
Colour:	According to product specification
Odour:	Characteristic

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- **Change in condition**
Melting point/Melting range: Undetermined.
Boiling point/Boiling range: Undetermined.
- **Flash point:** Not applicable.
- **Self-igniting:** Product is not selfigniting.
- **Danger of explosion:** Product does not present an explosion hazard.
- **Density:** Not determined.
- **Solubility in / Miscibility with water:** Not miscible or difficult to mix.
- **pH-value at 20°C:** 2.5

10 Stability and reactivity

- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Dangerous reactions** No dangerous reactions known.
- **Dangerous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

- **Acute toxicity:**
 - **LD/LC50 values relevant for classification:**
- | | |
|--------------------------------|-------------------------|
| Acidic adhesive monomer | |
| Oral | LD50 > 2000 mg/kg (rat) |
- **Primary irritant effect:**
 - **on the skin:** Irritant to skin and mucous membranes.
 - **on the eye:** Irritating effect.
 - **Sensitization:** Sensitization possible through skin contact.
 - **Additional toxicological information:**
 The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
 Irritant
 - **Sensitisation** May cause sensitisation by skin contact.

12 Ecological information

- **Additional ecological information:**
- **General notes:**
 Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
 Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

13 Disposal considerations

- **Product:**
- **Recommendation**
 Must not be disposed together with household garbage. Do not allow product to reach sewage system.

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- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- **Maritime transport IMDG:**
- **Marine pollutant:** No

15 Regulatory information

- **Labelling according to EU guidelines:**
The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials.
- **Code letter and hazard designation of product:**
 Xi Irritant
- **Hazard-determining components of labelling:**
Hydroxypropylmethacrylate
- **Risk phrases:**
 36/38 Irritating to eyes and skin.
 43 May cause sensitisation by skin contact.
- **Safety phrases:**
 24 Avoid contact with skin.
 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
 28 After contact with skin, wash immediately with plenty of water.
 37 Wear suitable gloves.
- **Special labelling of certain preparations:**
Contains 2-hydroxyethyl methacrylate, Hydroxypropylmethacrylate, benzoyl peroxyde. May produce an allergic reaction.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Department issuing MSDS:** Scientific departement
- **Contact:** Tel.: +49 (0)4721-719-0