

Safety Data Sheet

acc. to OSHA HCS

Printing date 05/02/2022

Reviewed on 05/02/2022

1 Identification

- **Product identifier**
- **Trade name:** *Bifix Temp base*
- **Application of the substance / the mixture** *Dental luting cement*
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
*VOCO GmbH
Anton-Flettner-Str. 1-3
D-27472 Cuxhaven*
- **Information department:** *Scientific department tel. +49 (0)4721-719-0*
- **Emergency telephone number:** *Scientific department tel. +49 (0)4721-719-0*

2 Hazard(s) identification

*Health effects are based on the unmixed/uncured material.
Under FDA regulations this product is classified as a medical device.
Medical devices are exempt from the labelling provisions of GHS according to the Hazard Communication Standard (HCS).*

- **Classification of the substance or mixture**



GHS07

*Eye Irrit. 2A H319 Causes serious eye irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.*

- **Label elements**
- **Hazard pictograms**



GHS07

- **Hazard statements**
*Causes serious eye irritation.
May cause an allergic skin reaction.*
- **Precautionary statements**
*Wear protective gloves / eye protection.
Wear protective clothing.
If on skin: Wash with plenty of water.
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.
Continue rinsing.
If skin irritation or rash occurs: Get medical advice/attention.
If eye irritation persists: Get medical advice/attention.*
- **Other hazards** *Use only for intended scope of application*
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*

3 Composition/information on ingredients

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

- **Dangerous components:**

CAS: 72869-86-4	Urethanedimethacrylate	5-10%
	Skin Sens. 1B, H317	

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Trade name: **Bifix Temp base**

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CAS: 109-16-0	Triethylene glycol dimethacrylate ↓ Skin Sens. 1, H317	5-10%
	Catalyst ⚠ Eye Dam. 1, H318 ↓ Acute Tox. 4, H302	1-2.5%

4 First-aid measures

- **Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:** Seek medical treatment in case of complaints.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **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.
- **Protective Action Criteria for Chemicals**

· PAC-1:

CAS: 72869-86-4	Urethanedimethacrylate	120 mg/m ³
CAS: 109-16-0	Triethylene glycol dimethacrylate	33 mg/m ³

· PAC-2:

CAS: 72869-86-4	Urethanedimethacrylate	1,300 mg/m ³
CAS: 109-16-0	Triethylene glycol dimethacrylate	360 mg/m ³

· PAC-3:

CAS: 72869-86-4	Urethanedimethacrylate	7,900 mg/m ³
CAS: 109-16-0	Triethylene glycol dimethacrylate	2,100 mg/m ³

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Trade name: *Bifix Temp base*

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7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
For dental use only.
Observe the instructions for use.
- **Information about protection against explosions and fires:** *No special measures required.*
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** *No special requirements.*
- **Information about storage in one common storage facility:** *Not required.*
- **Further information about storage conditions:** *See storage instructions on package*
- **Specific end use(s)** *No further relevant information available.*

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** *No further data; see item 7.*
- **Control parameters**
- **Components 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 that were valid during the creation were used as basis.*
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures for handling chemicals should be followed.
- **Breathing equipment:** *Not required.*
- **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.
- **Eye protection:** *Safety glasses*

9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Pasty
Color:	Cream colored
Odor:	Characteristic
Odor threshold:	Not determined.
- **pH-value:** *Not determined.*
- **Change in condition**

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

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Trade name: **Bifix Temp base**

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· Flash point:	101 °C (213.8 °F)
· Flammability (solid, gaseous):	Not applicable.
· Decomposition temperature:	Not determined.
· Auto igniting:	Product is not selfigniting.
· Danger of explosion:	Product does not present an explosion hazard.
· Density:	Not determined.
· Relative density	Not determined.
· Vapor density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with Water:	Not miscible or difficult to mix.
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
· Dynamic:	Not determined.
· Kinematic:	Not determined.
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:**
Testing according to ISO 10993-1/10993-10 showed no skin irritation for this product when fully cured
No irritant effect.
- **on the eye:** Irritating effect.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:**
The product shows the following dangers according to internally approved calculation methods for preparations:
Irritant
- **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

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· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (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.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|--|-----------------|
| · UN-Number | Void |
| · DOT, ADR, ADN, IMDG, IATA | Void |
| · UN proper shipping name | - |
| · DOT, ADR, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | - |
| · DOT, ADR, ADN, IMDG, IATA | Void |
| · Class | Void |
| · Packing group | - |
| · DOT, ADR, IMDG, IATA | Void |
| · Environmental hazards: | |
| · Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · UN "Model Regulation": | Void |

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Trade name: **Bifix Temp base**

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15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.

· **Sara**

· **Section 355 (extremely hazardous substances):**

None of the ingredients are listed.

· **Section 313 (Specific toxic chemical listings):**

None of the ingredients are listed.

· **TSCA (Toxic Substances Control Act):**

*One or more substances contained in this material are not listed on the TSCA Inventory.
 Contact VOCO for more information.*

· **Hazardous Air Pollutants**

None of the ingredients is listed.

· **Proposition 65**

· **Chemicals known to cause cancer:**

None of the ingredients are listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients are listed

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients are listed

· **Chemicals known to cause developmental toxicity:**

None of the ingredients are listed

· **Cancerogenity categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients are listed

· **TLV (Threshold Limit Value)**

Contact VOCO for more information.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients are listed

16 Other information

The information contained herein is based on our present knowledge and is believed to be correct at the date issued. The information is subject to change without notice. However, all information, statements, recommendations or suggestions shall not constitute any guarantee, representation or warranty, expressed or implied.

Final determination whether the product is fit and suitable for a particular purpose and the user's method of use or application is the sole responsibility of the user.

· **Department issuing SDS:** Scientific department

· **Contact:** Tel.: +49 (0)4721-719-0

· **Date of preparation / last revision** 05/02/2022 / 5

· **Abbreviations and acronyms:**

Acute Tox. 4: Acute toxicity – Category 4

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

Skin Sens. 1: Skin sensitisation – Category 1

Skin Sens. 1B: Skin sensitisation – Category 1B

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1 Identification

- **Product identifier**
- **Trade name:** *Bifix Temp catalyst*
- **Application of the substance / the mixture** *Dental luting cement*
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
*VOCO GmbH
Anton-Flettner-Str. 1-3
D-27472 Cuxhaven*
- **Information department:** *Scientific department tel. +49 (0)4721-719-0*
- **Emergency telephone number:** *Scientific department tel. +49 (0)4721-719-0*

2 Hazard(s) identification

- **Classification of the substance or mixture**



GHS07

Skin Sens. 1 H317 May cause an allergic skin reaction.

- **Additional information:**

Health effects are based on the unmixed/uncured material.

Under FDA regulations this product is classified as a medical device.

Medical devices are exempt from the labelling provisions of GHS according to the Hazard Communication Standard (HCS).

- **Label elements**
- **Hazard pictograms**



GHS07

- **Hazard statements**

May cause an allergic skin reaction.

- **Precautionary statements**

Wear protective gloves / protective clothing.

If on skin: Wash with plenty of water.

If skin irritation or rash occurs: Get medical advice/attention.

- **Other hazards** *Use only for intended scope of application*

- **Results of PBT and vPvB assessment**

- **PBT:** *Not applicable.*

- **vPvB:** *Not applicable.*

3 Composition/information on ingredients

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

- **Dangerous components:**

CAS: 109-16-0	Triethylene glycol dimethacrylate <i>Skin Sens. 1, H317</i>	5-10%
CAS: 72869-86-4	Urethanedimethacrylate <i>Skin Sens. 1B, H317</i>	5-10%
	benzoyl peroxyde <i>Org. Perox. B, H241</i> <i>Eye Irrit. 2A, H319; Skin Sens. 1, H317</i>	≤2.5%

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Trade name: Bifix Temp catalyst

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4 First-aid measures

- **Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:** Seek medical treatment in case of complaints.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **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.
- **Protective Action Criteria for Chemicals**

· PAC-1:

CAS: 109-16-0	Triethylene glycol dimethacrylate	33 mg/m ³
CAS: 72869-86-4	Urethanedimethacrylate	120 mg/m ³
	benzoyl peroxyde	15 mg/m ³

· PAC-2:

CAS: 109-16-0	Triethylene glycol dimethacrylate	360 mg/m ³
CAS: 72869-86-4	Urethanedimethacrylate	1,300 mg/m ³
	benzoyl peroxyde	1,200 mg/m ³

· PAC-3:

CAS: 109-16-0	Triethylene glycol dimethacrylate	2,100 mg/m ³
CAS: 72869-86-4	Urethanedimethacrylate	7,900 mg/m ³
	benzoyl peroxyde	7,000 mg/m ³

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
For dental use only.
Observe the instructions for use.
- **Information about protection against explosions and fires:** No special measures required.

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Trade name: *Bifix Temp catalyst*

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- *Conditions for safe storage, including any incompatibilities*
- *Storage:*
- *Requirements to be met by storerooms and receptacles:* No special requirements.
- *Information about storage in one common storage facility:* Not required.
- *Further information about storage conditions:* See storage instructions on package
- *Specific end use(s)* No further relevant information available.

8 Exposure controls/personal protection

- *Additional information about design of technical systems:* No further data; see item 7.
- *Control parameters*
- *Components 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 that were valid during the creation were used as basis.
- *Exposure controls*
- *Personal protective equipment:*
- *General protective and hygienic measures:*
The usual precautionary measures for handling chemicals should be followed.
- *Breathing equipment:* Not required.
- *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.
- *Eye protection:* Not required.

9 Physical and chemical properties

- *Information on basic physical and chemical properties*

- *General Information*

- *Appearance:*

· <i>Form:</i>	<i>Pasty</i>
· <i>Color:</i>	<i>Transparent</i>
· <i>Odor:</i>	<i>Characteristic</i>
· <i>Odor threshold:</i>	<i>Not determined.</i>

- *pH-value:* *Not determined.*

- *Change in condition*

· <i>Melting point/Melting range:</i>	<i>Undetermined.</i>
· <i>Boiling point/Boiling range:</i>	<i>Undetermined.</i>

- *Flash point:* *101 °C (213.8 °F)*

- *Flammability (solid, gaseous):* *Not applicable.*

- *Decomposition temperature:* *Not determined.*

- *Auto igniting:* *Product is not selfigniting.*

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

- *Density:* *Not determined.*

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Trade name: *Bifix Temp catalyst*

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- | | |
|---|---|
| · Relative density | <i>Not determined.</i> |
| · Vapor density | <i>Not determined.</i> |
| · Evaporation rate | <i>Not determined.</i> |
| · Solubility in / Miscibility with Water: | <i>Not miscible or difficult to mix.</i> |
| · Partition coefficient (n-octanol/water): | <i>Not determined.</i> |
| · Viscosity: | |
| Dynamic: | <i>Not determined.</i> |
| Kinematic: | <i>Not determined.</i> |
| · Other information | <i>No further relevant information available.</i> |

10 Stability and reactivity

- **Reactivity** *No further relevant information available.*
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** *No decomposition if used according to specifications.*
- **Possibility of hazardous reactions** *No dangerous reactions known.*
- **Conditions to avoid** *No further relevant information available.*
- **Incompatible materials:** *No further relevant information available.*
- **Hazardous decomposition products:** *No dangerous decomposition products known.*

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:**
*Testing according to ISO 10993-1/10993-10 showed no skin irritation for this product when fully cured
No irritant effect.*
- **on the eye:** *No irritating effect.*
- **Sensitization:** *Sensitization possible through skin contact.*
- **Additional toxicological information:**
- **Carcinogenic categories**

· IARC (International Agency for Research on Cancer)	
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benzoyl peroxyde

3

· NTP (National Toxicology Program)	
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None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)	
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None of the ingredients is listed.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** *No further relevant information available.*
- **Persistence and degradability** *No further relevant information available.*
- **Behavior in environmental systems:**
- **Bioaccumulative potential** *No further relevant information available.*
- **Mobility in soil** *No further relevant information available.*

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Trade name: **Bifix Temp catalyst**

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- **Additional ecological information:**
- **General notes:**
*Water hazard class 1 (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.*
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|--|-----------------|
| · UN-Number | - |
| · DOT, ADR, ADN, IMDG, IATA | Void |
| · UN proper shipping name | - |
| · DOT, ADR, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | - |
| · DOT, ADR, ADN, IMDG, IATA | - |
| · Class | Void |
| · Packing group | - |
| · DOT, ADR, IMDG, IATA | Void |
| · Environmental hazards: | |
| · Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · UN "Model Regulation": | Void |

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.
- **Sara**

· **Section 355 (extremely hazardous substances):**

None of the ingredients are listed.

· **Section 313 (Specific toxic chemical listings):**

None of the ingredients are listed.

· **TSCA (Toxic Substances Control Act):**

*One or more substances contained in this material are not listed on the TSCA Inventory.
 Contact VOCO for more information.*

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Trade name: **Bifix Temp catalyst**

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· Hazardous Air Pollutants
None of the ingredients is listed.
· Proposition 65
· Chemicals known to cause cancer:
None of the ingredients are listed.
· Chemicals known to cause reproductive toxicity for females:
None of the ingredients are listed
· Chemicals known to cause reproductive toxicity for males:
None of the ingredients are listed
· Chemicals known to cause developmental toxicity:
None of the ingredients are listed
· Carcinogeny categories
· EPA (Environmental Protection Agency)
None of the ingredients are listed
· TLV (Threshold Limit Value)
Contact VOCO for more information.
· NIOSH-Ca (National Institute for Occupational Safety and Health)
None of the ingredients are listed

16 Other information

The information contained herein is based on our present knowledge and is believed to be correct at the date issued. The information is subject to change without notice. However, all information, statements, recommendations or suggestions shall not constitute any guarantee, representation or warranty, expressed or implied.

Final determination whether the product is fit and suitable for a particular purpose and the user's method of use or application is the sole responsibility of the user.

· **Department issuing SDS:** Scientific department

· **Contact:** Tel.: +49 (0)4721-719-0

· **Date of preparation / last revision** 05/02/2022 / 7

· **Abbreviations and acronyms:**

Org. Perox. B: Organic peroxides – Type B

Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

Skin Sens. 1: Skin sensitisation – Category 1

Skin Sens. 1B: Skin sensitisation – Category 1B