1 Identification

- **Product identifier**
- **Trade name:** Bifix SE 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**
  
  !
  
  Eye Irrit. 2A  H319  Causes serious eye irritation.
  Skin Sens. 1B  H317  May cause an allergic skin reaction.

- **Label elements**
  - **Hazard pictograms** GHS07
  - **Signal word** Warning
  - **Hazard statements** Causes serious eye irritation. May cause an allergic skin reaction.
  - **Precautionary statements**
    Wear protective gloves / eye protection.
    Wear protective clothing.
    If skin irritation or rash occurs: Get medical advice/attention.
    If eye irritation persists: Get medical advice/attention.
    Dispose of contents/container in accordance with local/regional/national/international regulations.
  - **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.

<table>
<thead>
<tr>
<th>Dangerous components:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1830-78-0 Glycerindimethacrylate</td>
<td>Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335 5-10%</td>
</tr>
<tr>
<td>Catalyst</td>
<td>Eye Dam. 1, H318  Acute Tox. 4, H302 1-2.5%</td>
</tr>
<tr>
<td>Initiator</td>
<td>Acute Tox. 3, H301  ≤ 2.5%</td>
</tr>
</tbody>
</table>

4 First-aid measures

- **Description of first aid measures**
- **General information:** No special measures required.

(Contd. on page 2)
5 Fire-fighting measures

- Extinguishing media
  - Suitable extinguishing agents:
    - CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
  - 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: No dangerous substances are released.

7 Handling and storage

- Handling:
  - Precautions for safe handling:
    - For dental use only.
    - No special measures required.
  - 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: See storage instructions on package
    - Information about storage in one common storage facility: Not required.
    - Further information about storage conditions: None.

- 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.
Trade name: Bifix SE Base

- Protection of hands: Not required.
- Material of gloves: Not required.
- Eye protection: Safety glasses

### 9 Physical and chemical properties

#### Information on basic physical and chemical properties

- **General Information**
  - **Form:** Pasty
  - **Color:** According to product specification
  - **Odor:** Characteristic

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

- **Change in condition**
  - **Melting point/Melting range:** Undetermined.
  - **Boiling point/Boiling range:** Undetermined.

- **Flash point:** Not applicable.

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

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

- **Density at 20 ºC (68 ºF):** 1.86 g/cm³ (15.522 lbs/gal)

- **Solubility in / Miscibility with Water:** Not miscible or difficult to mix.

- **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
  - on the eye:
    - Irritating effect.

- **Sensitization:** Sensitization possible through skin contact.

- **Additional toxicological information:**
  - The product is not subject to classification according to internally approved calculation methods for preparations:

(Contd. on page 4)
Trade name: Bifix SE Base

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

- Carcinogenic categories
  - IARC (International Agency for Research on Cancer)
    128-37-0 2,6-di-tert-butyl-p-cresol
  - NTP (National Toxicology Program)
    None of the ingredients is listed.
  - 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:
    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: Smaller quantities can be disposed of with household waste.
- 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: Void
  - Class: Void

- Packing group
  - DOT, ADR, IMDG, IATA: Void

- Environmental hazards:
  - Marine pollutant: No

- Special precautions for user: Not applicable.
Trade name: Bifix SE Base

- Transport in bulk according to Annex II of MARPOL 73/78 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
  - 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.
  - Proposition 65
    None of the ingredients are listed.
  - 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)
    Initiator: I (oral)
    TLV (Threshold Limit Value established by ACGIH)
    128-37-0 2,6-di-tert-butyl-p-cresol A4
    NIOSH-Ca (National Institute for Occupational Safety and Health)
    None of the ingredients are listed.

- GHS label elements
  - The product is classified and labeled according to the Globally Harmonized System (GHS).
  - Hazard pictograms: GHS07
  - Signal word: Warning
  - Hazard statements
    - Causes serious eye irritation.
    - May cause an allergic skin reaction.
  - Precautionary statements
    - Wear protective gloves / eye protection.
    - Wear protective clothing.
    - If skin irritation or rash occurs: Get medical advice/attention.
    - If eye irritation persists: Get medical advice/attention.
    - Dispose of contents/container in accordance with local/regional/national/international regulations.

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** 09/20/2016 / 11
- **Abbreviations and acronyms:**
  - ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
  - IMDG: International Maritime Code for Dangerous Goods
  - DOT: US Department of Transportation
  - IATA: International Air Transport Association
  - ACGIH: American Conference of Governmental Industrial Hygienists
  - EINECS: European Inventory of Existing Commercial Chemical Substances
  - ELINCS: European List of Notified Chemical Substances
  - CAS: Chemical Abstracts Service (division of the American Chemical Society)
  - PBT: Persistent, Bioaccumulative and Toxic
  - vPvB: very Persistent and very Bioaccumulative
  - NIOSH: National Institute for Occupational Safety
  - OSHA: Occupational Safety & Health
  - TLV: Threshold Limit Value
  - PEL: Permissible Exposure Limit
  - REL: Recommended Exposure Limit
  - Acute Tox. 3: Acute toxicity – Category 3
  - Acute Tox. 4: Acute toxicity – Category 4
  - Skin Irrit. 2: Skin corrosion/irritation – Category 2
  - Eye Dam. 1: Serious eye damage/eye irritation – Category 1
  - Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A
  - Skin Sens. 1B: Skin sensitisation – Category 1B
  - STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

* Data compared to the previous version altered.
1 Identification

- **Product identifier**
  - **Trade name:** Bifix SE 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

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**
The product is classified according to the Globally Harmonized System (GHS).

![Warning]

- **Skin Irrit. 2** H315 Causes skin irritation.
- **Skin Sens. 1** H317 May cause an allergic skin reaction.

- **Eye Irrit. 2B** H320 Causes eye irritation.

- **Label elements**
  - **Hazard pictograms** GHS07
  - **Signal word** Warning

- **Hazard statements**
  - Causes skin and eye irritation.
  - May cause an allergic skin reaction.

- **Precautionary statements**
  - Wear protective gloves / eye protection.
  - Wear protective clothing.
  - 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.
  - Dispose of contents/container in accordance with local/regional/national/international regulations.

- **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.

<table>
<thead>
<tr>
<th>Dangerous components:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1830-78-0 Glycerindimethacrylate</td>
<td>5-10%</td>
</tr>
<tr>
<td>Skin Irrit. 2; H315; Eye Irrit. 2A; H319; STOT SE 3; H335</td>
<td></td>
</tr>
<tr>
<td>Acidic adhesive monomer</td>
<td>5-10%</td>
</tr>
<tr>
<td>Skin Corr. 1B, H314; Eye Dam. 1; H318</td>
<td></td>
</tr>
</tbody>
</table>

(Contd. on page 2)
Trade name: Bifix SE catalyst

<table>
<thead>
<tr>
<th>Reference Number</th>
<th>Component</th>
<th>Skin Irrit.</th>
<th>Eye Irrit.</th>
<th>Skin Sens.</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>1565-94-2</td>
<td>BIS GMA</td>
<td>2, H315</td>
<td>2A, H319</td>
<td>1, H317</td>
<td>5-10%</td>
</tr>
<tr>
<td>27813-02-1</td>
<td>Hydroxypropylmethacrylate</td>
<td>2, H315</td>
<td>2A, H319</td>
<td>1, H317</td>
<td>≤ 2.5%</td>
</tr>
<tr>
<td>Benzoil peroxyde</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>≤ 2.5%</td>
</tr>
</tbody>
</table>

**4 First-aid measures**

- **Description of first aid measures**
  - **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. If symptoms persist, consult a doctor.
  - **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: CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
  - Special hazards arising from the substance or mixture: No further relevant information available.
  - Advice for firefighters: 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.

**7 Handling and storage**

- **Handling:**
  - Precautions for safe handling: For dental use only.
  - 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: See storage instructions on package
    - Information about storage in one common storage facility: Not required.
  - Further information about storage conditions: Keep receptacle tightly sealed.

(Contd. on page 3)
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.
  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.
- Eye protection: Safety glasses

9 Physical and chemical properties

- Information on basic physical and chemical properties
- General Information
- Appearance:
  Form: Pasty
  Color: According to product specification
  Odor: Characteristic
- pH-value at 20 °C (68 °F): 2.5
- Change in condition
  Melting point/Melting range: Undetermined.
  Boiling point/Boiling range: Undetermined.
- Flash point: Not applicable.
- Auto igniting: Product is not selfigniting.
- Danger of explosion: Product does not present an explosion hazard.
- Density at 20 °C (68 °F): 1.87 g/cm³ (15.605 lbs/gal)
- Solubility in / Miscibility with Water: Not miscible or difficult to mix.
- 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**: No decomposition if used according to specifications.
- **Thermal decomposition / conditions to be avoided**: No further relevant information available.
- **Possibility of hazardous reactions**: No decomposition if used according to specifications.
- **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**:
    - **LD/LC50 values that are relevant for classification**:
      - **Acidic adhesive monomer**
        - Oral [LD50] > 2000 mg/kg (rat)
      - **Primary irritant effect**:
        - **on the skin**:
          - Testing according to ISO 10993-1/10993-10 showed no skin irritation for this product when fully cured.
        - **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)**
    - benzoyl peroxyde
    - 128-37-0 2,6-di-tert-butyl-p-cresol

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

- **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**: 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.
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
- UN proper shipping name
- Transport hazard class(es)
- Packing group
- 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.

15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
  - Sara
    - Section 355 (extremely hazardous substances):
      - None of the ingredients are listed.
    - Section 313 (Specific toxic chemical listings):
      - benzyol peroxyde
    - TSCA (Toxic Substances Control Act):
      - All ingredients are 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
    - None of the ingredients are listed.

* (Contd. on page 6)
Trade name: Bifix SE catalyst

- **TLV (Threshold Limit Value established by ACGIH)**
  Contact VOCO for more information.

- **NIOSH-Ca (National Institute for Occupational Safety and Health)**
  None of the ingredients are listed

- **GHS label elements**
  The product is classified and labeled according to the Globally Harmonized System (GHS).
  - **Hazard pictograms** GHS07
  - **Signal word** Warning

- **Hazard statements**
  Causes skin and eye irritation.
  May cause an allergic skin reaction.

- **Precautionary statements**
  Wear protective gloves / eye protection.
  Wear protective clothing.
  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.
  Dispose of contents/container in accordance with local/regional/national/international regulations.

*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** 09/20/2016 / 17

**Abbreviations and acronyms:**

- ACGIH: American Conference of Governmental Industrial Hygienists
- EINECS: European Inventory of Existing Commercial Chemical Substances
- ELINCS: European List of Notified Chemical Substances
- CAS: Chemical Abstracts Service (division of the American Chemical Society)
- LC50: Lethal concentration, 50 percent
- LD50: Lethal dose, 50 percent
- PBT: Persistent, Bioaccumulative and Toxic
- vPvB: very Persistent and very Bioaccumulative
- NIOSH: National Institute for Occupational Safety
- OSHA: Occupational Safety & Health
- TLV: Threshold Limit Value
- PEL: Permissible Exposure Limit
- REL: Recommended Exposure Limit
- Org. Perox. B: Organic peroxides – Type B
- Skin Corr. 1B: Skin corrosion/irritation – Category 1B
- Skin Irrit. 2: Skin corrosion/irritation – Category 2
- Eye Dam. 1: Serious eye damage/eye irritation – Category 1
- Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A
- Eye Irrit. 2B: Serious eye damage/eye irritation – Category 2B
- Skin Sens. 1: Skin sensitisation – Category 1
- STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

* Data compared to the previous version altered.