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

- 1.1 Product identifier
  - Trade name: x-tra base

- 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 filling material

- 1.3 Details of the supplier of the safety data sheet
  - Manufacturer/Supplier:
    - VOCO GmbH
    - Anton-Flettner-Str. 1-3
    - D-27472 Cuxhaven
  - Further information obtainable from: Scientific department tel. +49 (0)4721-719-0
  - 1.4 Emergency telephone number:
    - Poison Control Center Mainz +49 (0)6131-19240

SECTION 2: Hazards identification

- 2.1 Classification of the substance or mixture
  - Classification according to Regulation (EC) No 1272/2008
    - Skin Sens. 1 H317 May cause an allergic skin reaction.

- 2.2 Label elements
  - Labeling according to Regulation (EC) No 1272/2008
    - As a medical device the product is not subject to labelling regulations under 1272/2008/EC.
  - Hazard pictograms
    - GHS07
  - Hazard statements
    - May cause an allergic skin reaction.
  - Precautionary statements
    - Wear protective gloves / 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 occurs: Get medical advice/attention.
    - If eye irritation persists: Get medical advice/attention.
    - IF ON SKIN: Wash with plenty of water.
    - Dispose of contents/container in accordance with local/regional/national/international regulations.

- 2.3 Other hazards
  - Use only for intended scope of application
  - Results of PBT and vPvB assessment
    - PBT: Not applicable.
    - vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

- 3.2 Chemical characterisation: Mixtures
  - Description: Mixture of substances listed below with nonhazardous additions.

<table>
<thead>
<tr>
<th>Dangerous components:</th>
<th>BIS-EMA</th>
<th>Aquatic Chronic 4, H413</th>
<th>Aliphatic dimethacrylate</th>
<th>Skin Irrit. 2, H315; Eye Irrit. 2, H319</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS: 41637-38-1</td>
<td></td>
<td>10-25%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EC number: 609-946-4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SECTION 4: First aid measures

- 4.1 Description of first aid measures
  - General information: No special measures required.
  - After inhalation: Supply fresh air; consult doctor in case of complaints.
  - After skin contact:
    - Immediately wash with water and soap and rinse thoroughly.
    - If skin irritation continues, consult a doctor.
SECTION 5: Firefighting measures

- 5.1 Extinguishing media
  - Suitable extinguishing agents: Use fire extinguishing methods suitable to surrounding conditions.

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

- 5.3 Advice for firefighters
  - Protective equipment: No special measures required.

SECTION 6: Accidental release measures

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

- 6.2 Environmental precautions: Do not allow to enter sewers/surface or ground water.

- 6.3 Methods and material for containment and cleaning up: Pick up mechanically.

- 6.4 Reference to other sections: No dangerous substances are released.

SECTION 7: Handling and storage

- 7.1 Precautions for safe handling: For dental use only.

- 7.2 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.

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

SECTION 8: Exposure controls/personal protection

- Additional information about design of technical facilities: No further data; see item 7.

- 8.1 Control parameters
  - 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.

- 8.2 Exposure controls
  - 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.

Protective gloves
SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties
General Information
- Appearance:
  - Form: Pasty
  - Colour: Beige
- Odour: Characteristic
- pH-value: Not determined.
- Change in condition
  - Melting point/Melting range: Undetermined.
  - Boiling point/Boiling range: Undetermined.
- Flash point: Not applicable.
- Self-igniting: Product is not self-igniting.
- Danger of explosion: Product does not present an explosion hazard.
- Density: Not determined.
- Solubility in / Miscibility with water: Not miscible or difficult to mix.
- Viscosity:
  - Dynamic: Not determined.
  - Kinematic: Not determined.

9.2 Other information
No further relevant information available.

SECTION 10: Stability and reactivity

10.1 Reactivity
No further relevant information available.

10.2 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.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
- Acute toxicity: Based on available data, the classification criteria are not met.
- Primary irritant effect:
- Skin corrosion/irritation:
  Testing according to ISO 10993-1/10993-10 showed no skin irritation for this product when fully cured
- Serious eye damage/irritation: Based on available data, the classification criteria are not met.
- Respiratory or skin sensitisation:
  May cause an allergic skin reaction.
- CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)
- Germ cell mutagenicity: Based on available data, the classification criteria are not met.
- Carcinogenicity: Based on available data, the classification criteria are not met.
 SECTION 12: Ecological information

- 12.1 Toxicity
  - Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability: No further relevant information available.
- 12.3 Bioaccumulative potential: No further relevant information available.
- 12.4 Mobility in soil: No further relevant information available.
- 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.

- 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 considerations

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

 SECTION 14: Transport information

- 14.1 UN-Number
  - ADR, ADN, IMDG, IATA: Void
- 14.2 UN proper shipping name
  - ADR, ADN, IMDG, IATA: Void
- 14.3 Transport hazard class(es)
  - ADR, ADN, IMDG, IATA: Void
- 14.4 Packing group
  - ADR, IMDG, IATA: Void
- 14.5 Environmental hazards:
  - Marine pollutant: No
- 14.6 Special precautions for user
  - Not applicable.
- 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
  - Not applicable.
- UN "Model Regulation": Void

(Contd. on page 5)
SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
  - Directive 2012/18/EU
  - Named dangerous substances - ANNEX I None of the ingredients is listed.
  - REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

SECTION 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 SDS:** Scientific department
- **Contact:** Tel.: +49 (0)4721-719-0
- **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
  - IATA: International Air Transport Association
  - GHS: Globally Harmonised System of Classification and Labelling of Chemicals
  - 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
  - Skin Irrit. 2: Skin corrosion/irritation – Category 2
  - Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
  - Skin Sens. 1: Skin sensitisation – Category 1
  - Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4
- **Data compared to the previous version altered.**