# Safety Data Sheet
according to 1907/2006/EC, Article 31

**Date of issue:** 01.02.2017  
**Version:** 1  
**Printing date:** 27.02.2017

## 1. Identification of the substance/mixture and of the company/undertaking

<table>
<thead>
<tr>
<th><strong>Product Identifier</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trade name:</strong> VITA ADIVA T-BOND II</td>
</tr>
<tr>
<td><strong>Use of the preparation:</strong> Dental product</td>
</tr>
<tr>
<td><strong>Details of the supplier of the safety data sheet:</strong></td>
</tr>
</tbody>
</table>
| **Manufacturer/supplier:** Harvard Dental International GmbH, Margaretenstraße 2-4, 15366 Hoppegarten, Germany  
info@harvard-dental-international.de |
| **Emergency telephone number:** + 49 (0) 30 99 28 978-0 (Quality Management) |

## 2. Hazards identification

### Classification of the substance or mixture:

<table>
<thead>
<tr>
<th><strong>Classification according to Regulation (EC) No 1272/2008:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Flam. Liq. 2, H225 Highly flammable liquid and vapour</td>
</tr>
</tbody>
</table>

### Information concerning particular hazards for human and environment:

The product has to be labeled due to calculation procedure for the “General Classification guideline for preparations of the EU” in the latest version.

#### Label elements

- **Labeling according to Regulation (EC) 1272/2008:**
- **Hazard pictograms**

### Signal word

- **Danger**

### Hazard statements

- **H225** Highly flammable liquid and vapour

### Precautionary statements

- **P210** Keep away from heat/sparks/open flames/hot surfaces. – No smoking.

### Labeling according to EU guidelines:

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body; are exempted from the provisions of Regulation (EC) No. 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

### Other hazards

- **Results of PBT and vPvB assessment**
  - **PBT:** not applicable
  - **vPvB:** not applicable

## 3. Composition/Information on Ingredients

### Chemical characterization:

**Description:**
Solution of methacrylates, catalysts and stabilizers in ethanol

**Hazardous components:**
- 64-17-5 (CAS-No.)  
  - **Ethanol**  
  - GHS02, H225
4. **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 opened eye for several minutes under running water and consult a doctor
   after swallowing: Consult a physician.

5. **Fire fighting measures**

   **Extinguishing media:**
   CO₂, powder, water spray.
   Use extinguishing method and media suitable to surrounding fire.
   **Special hazards arising from the substance or mixture** No further relevant information available
   **Protective equipment** Wear self-contained respiratory protective equipment

6. **Accidental release measures**

   **Personal precautions, protective equipment and emergency procedures:**
   Do not inhale vapours/aerosols. Avoid substance contact. Ensure supply of fresh air in enclosed rooms
   **Environmental precautions:**
   Do not allow to enter drains/surface water/ground-water.
   **Methods for cleaning up:**
   Absorb with liquid binding material. Clean up affected area.
   **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:**
   This product should only be supplied or handled to dentists or dental technicians or upon their instructions.
   **Precautions for safe handling:** Observe normal care for working with chemicals
   **Information about fire and explosion protection:** Keep away from heat and fire. Take measure to prevent electrostatic charge
   **Storage:** Store at a dry place. Store tightly closed. Storage temperature <25°C.
   **Requirements at storerooms and containers:** Store only in the original containers
   **Further information on storage conditions:**
   Store away from food stuffs.
   **Specific end uses:** No further relevant information available
8. Exposure controls/personal protection

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

<table>
<thead>
<tr>
<th>CAS-No.</th>
<th>name</th>
<th>art</th>
<th>value</th>
<th>unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>64-17-5</td>
<td>Ethanol</td>
<td>TRGS 900</td>
<td>500</td>
<td>ml/m³ (ppm) or 960 mg/m³</td>
</tr>
</tbody>
</table>

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

General protective equipment:

Personal protective equipment:

General protective and 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

Hand protection

Protective gloves.

Due to missing tests no recommendation to the glove material can be given for the product.

Eye protection: safety glasses

Respiratory protection: Required, when aerosols are generated

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance

- Form: liquid
- Color: colorless
- Odor: characteristic

Safety relevant basic data

- Melting point/melting range: -114 °C
- Boiling point/boiling range: 78 °C.
- Flash point: 12 °C
- Ignition temperature: 425 °C.
- Danger of explosion: Lower limit of explosion 3.5 % Kühn-
  Upper limit of explosion 15 % Birett

- Density: 0.8 g/cm³
- Vapor pressure: n.d.
- pH: neutral

Solubility in/miscibility with:

- Water: soluble
- Content of solvents:

  Organic solvents: ethanol

10. Stability and reactivity

Thermal decomposition / conditions to be avoided

Possibility of hazardous reactions: no information available

Conditions to avoid: Heat, direct sunlight and radical starters. The product is stable by proper use. Avoid contact with alkali metals, hydrides, strong oxidizing agents, radical initiators.

Hazardous decomposition products: No information available.
11. Toxicological information
Acute toxicity: (ethanol)
LD$_{50}$ (oral, rat) 6200 mg/kg
Primary irritation:
skin: degreasing effect
eye: slight irritation
Sensitization: no information available
Additional toxicological information:
Allergic reactions 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.

12. Ecological information
General information: Avoid transfer into environment
Classification of water endangerment: WGK=1 (slightly polluting substance).

13. Disposal considerations
Product:
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.

14. Transport information
Land transport ADR/RID and GGVs/GGVE (Germany):
UN 1170 ETHANOL, 3, II
Sea transport IMDG:
UN 1170 ETHANOL, 3, II
EmS F-E S-D
Air transport ICAO-TI and IATA-DGR:
UN 1170 ETHANOL, 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.

15. Regulatory information
Classification according to EC-guidelines:
The product is a medical device according to EC-directive 93/42 EEC.
Chemical safety assessment:
A Chemical Safety Assessment has not been carried out.

16. Other information:
Changes compared with the previous version:
Adaptation according to 1907/2006/EG, Article 31

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