

# Safety Data Sheet

## according to 1907/2006/EC, Article 31

Date of issue: 24.09.2015  
Printing date: 28.09.2015

Version: 2

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

#### **Product Identifier**

**Trade name: Harvard Implant semi-permanent**

**Use of the preparation:** Dental product

#### **Details of the supplier of the safety data sheet:**

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:**

#### **Classification according to Regulation (EC) No 1272/2008:**

Skin Irrit. 2; H315 Causes skin irritation

Eye Irrit.. 2; H319 Causes serious eye irritation

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

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

#### **Label elements:**

#### **Labeling according to Regulation (EC) 1272/2008:**

#### **Hazard pictograms**



#### **Signal word**

Warning

#### **Hazard statements**

H315 Causes skin irritation

H319 Causes serious eye irritation

#### **Precautionary statements**

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

#### **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

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<b>3. <u>Composition/Information on Ingredients</u></b>
<p><b>Chemical characterization:</b> Mixture</p> <p><b>Description of the mixture:</b> Mixture of unsaturated esters, multifunctional methacrylates, silica, fillers (containing zinc)</p> <p><b>Hazardous components:</b>          Methacrylates [Index-No. 607-134-00-4] <span style="float: right;">GHS07, H315, H319</span></p>
<b>4. <u>First-aid measures</u></b>
<p><b>General information:</b> no special measures required</p> <p><b>after skin contact:</b> wash with plenty of water and soap</p> <p><b>after eye contact:</b> Rinse opened eye for several minutes under running water and consult a doctor</p> <p><b>after swallowing:</b> Seek medical advice immediately</p>
<b>5. <u>Fire fighting measures</u></b>
<p><b>Extinguishing media:</b>          CO<sub>2</sub>, powder, water spray.          Use extinguishing method and media suitable to surrounding fire</p> <p><b>Special hazards arising from the substance or mixture</b> No further relevant information available</p> <p><b>Protective equipment</b> Wear self-contained respiratory protective equipment</p>
<b>6. <u>Accidental release measures</u></b>
<p><b>Personal precautions, protective equipment and emergency procedures</b></p> <p><b>Environmental precautions:</b>          Do not allow to enter drains/surface water/ ground-water.</p> <p><b>Methods for cleaning up:</b>          Take up mechanically. Clean up affected area.</p> <p><b>Reference to other sections:</b>          See Section 7 for information on safe handling          See Section 8 for information on personal protection equipment          See Section 13 for disposal information</p>
<b>7. <u>Handling and storage</u></b>
<p><b>Handling:</b>          This product should only be supplied or handled to dentists or dental technicians or upon their instructions.</p> <p><b>Precautions for safe handling:</b> Observe normal care for working with chemicals</p> <p><b>Information about fire and explosion protection:</b> No special measures required</p> <p><b>Storage:</b>  <b>Requirements at storerooms and containers:</b> Store only in the original containers</p> <p><b>Further information on storage conditions:</b>          Store at dry place, storage temperatur &lt;20°C. Store away from food stuffs.</p> <p><b>Specific end uses:</b> No further relevant information available</p>

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#### 8. Exposure controls/personal protection

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

The product contains no relevant quantities of components with limit values to be supervised 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.  
 Keep away from foodstuffs and beverages.

##### **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**

<b>Form:</b>	paste		
<b>Color:</b>	Tooth colored		
<b>Odor:</b>	odorless		
	<u>Value</u>	<u>Unit</u>	<u>Method</u>

##### **Safety relevant basic data**

<b>Melting point/melting range:</b>	n.a.		
<b>Boiling point/boiling range:</b>	n.a.		
<b>Flash point:</b>	n.a.		
<b>Ignition temperature:</b>	Product is not selfigniting		
<b>Danger of explosion:</b>	None		
<b>Density:</b>	1,55 (20 °C)	g/cm <sup>3</sup>	
<b>Vapor pressure:</b>	Not applicable (non volatile)		
<b>Solubility in/miscibility with:</b>	slightly in toluene, organic solvents		
<b>Water:</b>	insoluble		
<b>Content of solvents:</b>	none		
<b>Organic solvents:</b>	none		

#### 10. Stability and reactivity

##### **Thermal decomposition / conditions to be avoided**

No decomposition if used according to specifications.

**Possibility of hazardous reactions:** No dangerous reaction known

**Conditions to avoid:** avoid heat, direct sunlight

**Incompatible materials:** Peroxides, metal powders, strong oxidizers, free radical initiators

**Hazardous decomposition products:** No dangerous decomposition products known.

#### 11. Toxicological information

Allergic reactions to methacrylates by chronic exposure to the product are possible

##### **Acute toxicity:**

##### **Primary irritation:**

**skin:** slight irritating

**eye:** irritating effect

**Sensitization:** no sensitizing effect known

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**Additional toxicological information:**

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****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

**General information:** Do not allow product into surface water or sanitary sewer system

**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)**

Not classified as dangerous goods in the meaning of transport regulations

**Sea transport IMDG**

Not classified as dangerous goods in the meaning of transport regulations

**Air transport ICAO-TI and IATA-DGR**

Not classified as dangerous goods in the meaning of transport regulations

**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.