

# Safety Data Sheet

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

Date of issue: 19.11.2021  
Printing date: 19.11.2021

Version: 3

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

#### **Product Identifier**

**Trade name: Harvard BioCal®-CAP**

**Use of the preparation:** Dental Product

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

#### **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:**

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

Skin Irrit. 2, H315 Causes skin irritation

Eye Dam. 1, H318 Causes serious eye damage

Skin Sens. 1; H317 May cause allergic skin reaction

#### **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**

Warning

#### **Hazard statements**

H315 Causes skin irritation

H318 Causes serious eye damage

H317 May cause allergic skin reaction

#### **Precautionary statements**

P280 Wear protective gloves/protective clothing/eye protection/face protection

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

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

#### **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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#### **3. Composition/Information on Ingredients**

**Chemical characterization:**

**Description:**

Mixture of several mineral oxides and methacrylates

**Hazardous components:**

Mineral oxides           GHS05, GHS07,     H315, H318, H317

Methacrylates           GHS07,               H315, H319, H335, H317

#### **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

**after inhalation:** fresh air

**after eye contact:** rinse opened eye for several minutes under running water and consult a doctor

**after swallowing:** If symptoms persist seek medical advice.

#### **5. Fire fighting measures**

**Extinguishing media:**

CO<sub>2</sub>, 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:**

Avoid contact with skin and eyes.

**Environmental precautions:**

Do not allow to enter drains/surface water/ ground-water.

**Methods for cleaning up:**

Take up mechanically. Forward for disposal. 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:** No special measures required

**Storage:** Store at a dry place. Store tightly closed. Store at 2 - 8°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

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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 limits of 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. 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**

<b>Form:</b>	paste		
<b>Color:</b>	white		
<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>	1,82 g/cm <sup>3</sup> (20 °C)
<b>Vapor pressure:</b>	Not applicable (non volatile)
<b>pH value</b>	10-12
<b>Solubility in/miscibility with:</b>	
<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:** No further relevant information available

**Incompatible materials:** No further relevant information available

**Hazardous decomposition products:** no information available.

