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1. <u>Identification of the substance/mixture and of the company/undertaking</u>
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:** 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: 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. <u>Exposure controls/personal protection</u>			
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. <u>Physical and chemical properties</u>			
Information on basic physical and chemical properties			
Appearance			
Form:	paste		
Color:	white		
Odor:	odorless		
	Value Unit Method		
Safety relevant basic data			
Melting point/melting range:	n.a.		
Boiling point/boiling range:	n.a.		
Flash point:	n.a.		
Ignition temperature:	Product is not selfigniting		
Danger of explosion:	none		
Density:	1,82 g/cm3 (20 °C)		
Vapor pressure:	Not applicable (non volatile)		
pH value	10-12		
Solubility in/miscibility with:			
Water:	insoluble		
Content of solvents:	none		
Organic solvents:	none		
10. <u>Stability and reactivity</u>			
Thermal decomposition / conditions to b			
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.			

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11.	Toxicological information		
	Acute toxicity: No further relevant information available		
	Primary irritation:		
	skin: may cause skin irritation		
	eye: strong caustic effect		
	Sensitization: Sensitization possible through skin contact		
	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.	12. <u>Ecological information</u>		
	Toxicity:		
	Aquatic toxicity: No further relevant information available		
Persistence and degradability: No further relevant information available			
Bioaccumulative potential No further relevant information available			
Mobility in soil No further relevant information available			
	Additional ecological information:		
	General information: Do not allow to enter into surface water or sanitary sewer system		
	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):		
	Not subject to transport regulations		
	Sea transport IMDG:		
	Not subject to transport regulations		
	Air transport ICAO-TI and IATA-DGR:		
	Not subject to 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:		
	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.		