

Safety Data Sheet

according to 1907/2006/EC, Article 31

Date of issue: 13.11.2019
Printing date: 13.11.2019

Version: 2

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:

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 4 - 20°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

| | | | |
|---------------|--------------|-------------|---------------|
| Form: | paste | | |
| Color: | white | | |
| Odor: | odorless | | |
| | <u>Value</u> | <u>Unit</u> | <u>Method</u> |

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/cm ³ (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. 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.

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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. Ecological information

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.