

Safety Data Sheet

according to 1907/2006/EC, Article 31

Date of issue: 17.06.2021
Printing date: 17.06.2021

Version: 1

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

Product Identifier

Trade name: Harvard BioCal® - RootSeal

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

2. Hazards identification

Classification of the substance or mixture:

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

Skin Irritation, Category 2; H315 Causes skin irritation

Eye Irritation, Category 2; H319 Causes serious eye irritation

STOT SE, Category 3, H335 May cause respiratory 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

H335 May cause respiratory irritation

Precautionary statements

P262 Do not get in eyes, on skin or on clothing.

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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3. Composition/Information on Ingredients

Chemical characterization: Mixture

Description of the mixture: Mixture of unsaturated esters, polyfunctional methacrylates, mineral oxides, zirconium dioxide, silica, initiator, stabilizer

Hazardous components:

Methacrylates

GHS07, H315, H319, H335

4. First-aid measures

General information: no special measures required

After skin contact: wash with plenty of water and soap

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

after swallowing: Seek medical advice immediately

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

Environmental precautions:

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

Methods for cleaning up:

Take up mechanically. 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:

Requirements at storerooms and containers: Store only in the original containers

Further information on storage conditions:

Store at dry place, at room temperature. 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 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

Form:	paste		
Color:	pale pink		
Odor:	nearly 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:	n.d.		
Danger of explosion:	none		
Density:	1,7 (20 °C)	g/cm ³	
Vapor pressure:	not applicable (non volatile)		
Solubility in/miscibility with:			
Water:	slightly		
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: 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

Acute toxicity:

Primary irritation:

skin: slight irritating

eye: irritating effect

Sensitization: no sensitizing effect known

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Additional toxicological information:

Allergic reactions to methacrylates 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**Toxicity:**

Aquatic toxicity: May cause long term adverse effect in the aquatic environment

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: Handle contaminated packaging in the same way as the substance itself.

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.

Sea transport IMDG

Not classified as dangerous goods.

Air transport ICAO-TI and IATA-DGR

Not classified as dangerous goods.

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:**

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.