

Safety Data Sheet

according to 1907/2006/EC, Article 31

Date of issue: 16.05.2018
 Printing date: 16.05.2018

Version: 4

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

Product Identifier

Trade name: Harvard Ionoresin Cem Extra – Powder
 Harvard Ionoresin Cem Extra OptiCaps® – Powder

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: void

Information concerning particular hazards for human and environment:

The product does not have 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: void

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

3. Composition/Information on Ingredients

Chemical characterization: Mixture

Description of the mixture: barium-fluoro-aluminosilicate glass powder, pigments, initiators

Hazardous components: none

4. First-aid measures

General information: no special measures required

after skin contact: wash with plenty of water and soap

after inhalation: supply with fresh air

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

after swallowing: seek medical advice if problems persist

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

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6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Avoid formation of dust.

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 (< 25°C, 78°F). Store away from food stuffs. Always store with lid on

Specific end uses: No further relevant information available

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:	Fine powder
Color:	white
Odor:	odorless

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	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:	Not determined		
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. Avoid heat and direct sunlight.			
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 dangerous decomposition products known.			
11. Toxicological information			
Acute toxicity:			
Primary irritation:			
skin: may cause skin irritation (aerosols)			
eye: irritating effect (aerosols)			
Sensitization: no sensitizing effect known			
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 undiluted product or large quantities of it 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			

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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 REACH-regulation (EC) No. 1907/2006, 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.