

Safety Data Sheet according to 1907/2006/EC, Article 31

Date of issue: 31.08.2022
Printing date: 31.08.2022

Version: 7

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

Product Identifier

Trade name: Harvard Cement normal setting, powder
Harvard Cement quick setting, powder
Harvard Cement 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

2. Hazards identification

Classification of the substance or mixture:

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

Acute aquatic toxicity, Category 1, H400 Very toxic to aquatic life

Chronic aquatic toxicity, Category 1, H410 Very toxic to aquatic life with long lasting effects

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

H400 Very toxic to aquatic life

H410 Very toxic to aquatic life with long lasting effects

Precautionary statements

P273 Avoid release to the environment

Labeling according to EU guidelines:

Medical devices 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).

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: Mixture of zinc oxide, magnesium oxide and pigments

Hazardous components:

Zinc oxide [CAS-No. 1314-13-2]	GHS09, H410, H411	80 – 100 %
--------------------------------	-------------------	------------

Safety Data Sheet

according to 1907/2006/EC, Article 31

Date of issue: 31.08.2022
 Printing date: 31.08.2022

Version: 7

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 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:
 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. Prevent fire fighting water from entering surface water or groundwater.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures:
 Avoid inhalation of dust.
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. Avoid generation of dust.
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, storage temperature < 25°C. Store away from food stuffs.
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.

Safety Data Sheet

according to 1907/2006/EC, Article 31

Date of issue: 31.08.2022
 Printing date: 31.08.2022

Version: 7

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:	powder		
Color:	yellowish		
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:	n.a. (non combustible)
Danger of explosion:	none
Density:	n.a.
Vapor pressure:	Not applicable (non volatile)
Solubility in/miscibility with:	slightly in toluene, organic solvents
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:** avoid heat, direct sunlight**Incompatible materials:** not known**Hazardous decomposition products:** no dangerous decomposition products known.**11. Toxicological information****Acute toxicity:** LD₅₀ (rat) >5000 mg/kg (zinc oxide)**Primary irritation:****skin:** slight irritating**eye:** irritating effect**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.

Safety Data Sheet

according to 1907/2006/EC, Article 31

Date of issue: 31.08.2022
 Printing date: 31.08.2022

Version: 7

12. <u>Ecological information</u>
<p>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 Classification of water endangerment: WGK = 2 (polluting substance).</p>
13. <u>Disposal considerations</u>
<p>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</p>
14. <u>Transport information</u>
<p>Land transport ADR/RID and GGVS/GGVE (Germany) ADR, RID UN 3077 UMWELTGEFÄHRDENDER STOFF, FEST N.A.G (Zinkoxid), 9, III Sea transport IMDG IMDG-Code UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide), 9, III EmS: F-A S-F Air transport ICAO-TI and IATA-DGR CAO, PAX UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide), 9, III</p> <p>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.</p>
15. <u>Regulatory information</u>
<p>Classification according to EC-guidelines: The product is a medical device according to MDR (EU) 2017/745. Chemical safety assessment: A Chemical Safety Assessment has not been carried out.</p>
16. <u>Other information:</u>
<p>Changes compared with the previous version: Notes on Directive 93/42/EEC removed</p> <p>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.</p>