

Safety Data Sheet

according to 1907/2006/EC, Article 31

Date of issue: 28.09.2015
 Printing date: 18.10.2016

Version: 3

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

Product Identifier

Trade name: **Harvard Polycarboxylat Cement – Powder**
Harvard Polycarboxylat 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 (Qualitätssicherung)

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 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: Mixture of zinc oxide, magnesium oxide and pigments

Hazardous components:

Zinc oxide [CAS-No. 1314-13-2]

GHS09, H410, H411

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| 4. <u>First-aid measures</u> |
| <p>General information: Seek medical advice, if symptoms occur, which can be caused by the product</p> <p>after skin contact: wash with plenty of water and soap</p> <p>after eye contact: Rinse opened eye for several minutes under running water and consult a doctor</p> <p>after swallowing: Seek medical advice immediately</p> |
| 5. <u>Fire fighting measures</u> |
| <p>Extinguishing media: Use extinguishing method and media suitable to surrounding fire</p> <p>Special hazards arising from the substance or mixture No further relevant information available</p> <p>Protective equipment Wear self-contained respiratory protective equipment. Prevent fire fighting water from entering surface water or groundwater.</p> |
| 6. <u>Accidental release measures</u> |
| <p>Personal precautions, protective equipment and emergency procedures: Avoid inhalation of dust.</p> <p>Environmental precautions: Do not allow to enter drains/surface water/ ground-water.</p> <p>Methods for cleaning up: Take up mechanically. Forward for disposal. Clean up affected area. Avoid generation of dust.</p> <p>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</p> |
| 7. <u>Handling and storage</u> |
| <p>Handling: This product should only be supplied or handled to dentists or dental technicians or upon their instructions.</p> <p>Precautions for safe handling: Observe normal care for working with chemicals</p> <p>Information about fire and explosion protection: No special measures required</p> <p>Storage: Requirements at storerooms and containers: Store only in the original containers</p> <p>Further information on storage conditions: Store at dry place, storage temperature < 25°C. Store away from food stuffs.</p> <p>Specific end uses: No further relevant information available</p> |
| 8. <u>Exposure controls/personal protection</u> |
| <p>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.</p> <p>Additional information: The lists valid during the making were used as basis</p> <p>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.</p> |

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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.

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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

Classification of water endangerment: WGK = 2 (polluting substance).

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)

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

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:

Adaptation according to 1907/2006/EG, 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.