

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, liquid
Harvard Cement quick setting, liquid
Harvard Cement OptiCaps[®], liquid

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 Corr. 1B; H314 Causes severe skin burns and eye damage

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

Danger

Hazard statements

H314 Causes severe skin burns and eye damage

Precautionary statements

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P280 Wear protective gloves/protective clothing/eye protection/face protection

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

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| 3. Composition/Information on Ingredients |
| <p>Chemical characterization: Description: Aqueous solution of phosphoric acid Hazardous components: CAS 7664-38-2 Phosphoric acid GHS05, H314 50 – 90 %</p> |
| 4. First-aid measures |
| <p>General information: Seek medical advice, if symptoms occur, which can be caused by the product after skin contact: Wash with plenty of water. Immediately remove contaminated clothing. after inhalation: Fresh air. Consult a doctor. after eye contact: Rinse opened eye for several minutes under running water and consult a doctor after swallowing: Make victim drink plenty of water. Avoid vomiting. . Do not attempt to neutralize. Seek medical advice.</p> |
| 5. Fire fighting measures |
| <p>Extinguishing media: Non combustible. In case of fire use extinguishing method and media suitable to surrounding fire. Special hazards arising from the substance or mixture Fire may cause evolution of oxides of phosphorus. Suppress vapors with water spray. Protective equipment Wear self-contained respiratory protective equipment</p> |
| 6. Accidental release measures |
| <p>Personal precautions, protective equipment and emergency procedures: Avoid substance contact.. Do not inhale vapours/aerosols. Ensure adequate ventilation. Environmental precautions: Do not allow to enter drains/surface water/ ground-water. Methods for cleaning up: Absorb with liquid binding and neutralizing material. Forward for disposal. Clean up affected area. Ensure adequate ventilation. 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. Handling and storage |
| <p>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: none Storage: Store at a dry place. Store tightly closed. Storage temperature < 25°C. Requirements at storerooms and containers: Store only in the original containers Further information on storage conditions: Store away from food stuffs. Avoid contact with alkalis, heavy-metal-containing components and combustibles Specific end uses: No further relevant information available</p> |

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8. Exposure controls/personal protection

Components with limits of values to be supervised at the workplace:

| CAS-No. | name | art | value | unit |
|-------------|-----------------|--------------|-------|--------------------|
| [7664-38-2] | Phosphoric acid | TRGS 900 AGW | 2 | mg/cm ³ |

type of exposure: inhalable fraction

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: | Liquid | | | | | | |
|---------------|--|--------|------|--------|--|--|--|
| Color: | colorless | | | | | | |
| Odor: | Faint odor | | | | | | |
| | <table border="1"> <thead> <tr> <th>Value</th> <th>Unit</th> <th>Method</th> </tr> </thead> <tbody> <tr> <td></td> <td></td> <td></td> </tr> </tbody> </table> | Value | Unit | Method | | | |
| Value | Unit | Method | | | | | |
| | | | | | | | |

Safety relevant basic data

Melting point/melting range: n.d.

Boiling point/boiling range: > 100 °C

Flash point: n.a.

Autoignition temperature: n.a. (non combustible)

Danger of explosion: none

Density: 1.7 g/cm³

Vapor pressure: Non volatile

pH: 1 - 2

Solubility in/miscibility with:

Water: Very soluble

Content of solvents: none

Organic solvents: none

10. Stability and reactivity

Thermal decomposition / conditions to be avoided

Conditions to avoid: Bases, metallic oxides most metals and metal alloys: Formation of hydrogen. Incompatible with iron/iron-containing compounds, steel, aluminium and their compounds.

Hazardous decomposition products: Fire may cause evolution of oxides of phosphorus.

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11. Toxicological information

Acute toxicity:

LD₅₀ (oral) Rat: 1530 mg/kg

Primary irritation:

skin: Caustic effect on skin and mucous membranes

eye: Strong caustic effect. Risk of blindness.

after inhalation: Irritation symptoms in the respiratory tract.

after ingestion: Strong caustic effect on mouth and throat.

Sensitization: not observed

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

General information: Anorganic substance. Does not cause biological oxygen deficit.

Harmful effect on aquatic organisms. Harmful effect due to pH shift.

Water pollution class: 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):

UN 1805 PHOSPHORSÄURE, LÖSUNG, 8, III

Sea transport IMDG:

UN 1805 PHOSPHORIC ACID, SOLUTION, 8, III

EmS: F-A S-B

Air transport ICAO-TI and IATA-DGR:

UN 1805 PHOSPHORIC ACID, SOLUTION, 8, 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 MDR (EU) 2017/745.

Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

16. Other information:

Changes compared with the previous version:

Notes on Directive 93/42/EEC removed

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.