

Safety Data Sheet

according to 1907/2006/EC, Article 31

Date of issue: 22.09.2015
 Printing date: 28.09.2015

Version: 2

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

Product Identifier

Trade name: Harvard PremiumFill

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:

Skin Irrit. 2, H315 Causes skin irritation

Eye Irrit. 2, H319 Causes serious eye irritation

Skin Sens. 1; H317 May cause allergic skin reaction

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

Warning

Hazard statements

H315 Causes skin irritation

H319 Causes serious eye irritation

H317 May cause allergic skin reaction

Precautionary statements

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

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

P302+P352 IF ON SKIN: Wash with plenty of soap and water

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. <u>Composition/Information on Ingredients</u> |
| <p>Chemical characterization:</p> <p>Description: mixture of urethanedimethacrylate-resin, glass fillers, silica, polymer powder, photoinitiator, accelerator, stabilizer</p> <p>Hazardous components: Methacrylates GHS07, H315, H319, H317, H335</p> |
| 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 inhalation: fresh air</p> <p>after eye contact: rinse with plenty of water and consult a doctor</p> <p>after swallowing: If symptoms persist consult a doctor</p> |
| 5. <u>Fire fighting measures</u> |
| <p>Extinguishing media: CO₂, powder, water spray. 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</p> |
| 6. <u>Accidental release measures</u> |
| <p>Personal precautions: not required</p> <p>Environmental precautions: Do not allow to enter drains/surface water/ ground-water.</p> <p>Methods for cleaning up: Pick up mechanically. Clean up affected area.</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>Information 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: Store at a dry place. Store tightly closed. Storage temperature <25°C.</p> <p>Requirements at storerooms and containers: Store only in the original containers</p> <p>Further information on storage conditions: Store away from food stuffs.</p> <p>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:

The product contains no relevant quantities of components with limits of 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. 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: | paste | | |
| Color: | tooth colored | | |
| Odor: | 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.d.

Ignition temperature:

n.d.

Danger of explosion:

none

Density:

1.93 (20°C) g/cm³

Vapor pressure:

n.a.

pH:

neutral

Solubility in/miscibility with:

Partially soluble in toluene, silicone oil

Water:

insoluble

Content of solvents:

none

Organic solvents:

none

10. Stability and reactivity

Thermal decomposition / conditions to be avoided

Possibility of hazardous reactions: no information available

Conditions to avoid: Heat, direct sunlight and radical starters. The product is stable by proper use. Avoid contact with alkali metals, hydrides, strong oxidizing agents, radical initiators.

Hazardous decomposition products: No information available.

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| 11. <u>Toxicological information</u> |
| <p>Acute toxicity: no data available</p> <p>Primary irritation:</p> <p>skin: irritant</p> <p>eye: irritant</p> <p>Sensitization: sensitization by skin contact possible</p> <p>Additional toxicological information:</p> <p>Allergic reactions to the product 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.</p> |
| 12. <u>Ecological information</u> |
| <p>General information: Avoid transfer into environment</p> <p>Classification of water endangerment: WGK=1 (slightly polluting substance).</p> |
| 13. <u>Disposal considerations</u> |
| <p>Product:</p> <p>Recommendation:</p> <p>Small quantities can be disposed of with household waste. Use proper landfill disposal or incineration in accordance with local, state and federal regulations.</p> <p>Uncleaned packaging:</p> <p>Recommendation: Disposal must be made according to official regulations</p> |
| 14. <u>Transport information</u> |
| <p>Land transport ADR/RID and GGVS/GGVE (Germany): no subject to transport regulations</p> <p>Sea transport IMDG: no subject to transport regulations</p> <p>Air transport ICAO-TI and IATA-DGR: no subject to transport regulations</p> |
| 15. <u>Regulatory information</u> |
| <p>Classification according to EC-guidelines:</p> <p>The product is a medical device according to EC-directive 93/42 EEC.</p> <p>Chemical safety assessment:</p> <p>A Chemical Safety Assessment has not been carried out.</p> |
| 16. <u>Other information:</u> |
| <p>Changes compared with the previous version:</p> <p>Adaptation according to 1907/2006/EG, Article 31</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> |