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

Date of issue: 25.02.2014 Printing date: 25.02.2014

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

Product Identifier

Trade name: HeyTec-M Use of the preparation: Dental product Details of the supplier of the safety data sheet: Manufacturer/supplier: HEYDENT GmbH Viktor Frankl Str. 20 86916 Kaufering Germany +49 8191 9737805 info@heydent.com

2. Hazards identification

Classification of the substance or mixture

Classification according to Regulation (EC) 1272/2008: void

Classification according to Directive 67/548/EEC or Directive 1999/45/EC: void

Information concerning particular hazards for human and environment:

The product does not have 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 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 dangerous substance Directive 1999/45/EWG.

Other hazards

Results of PBT and vPvB assessment

PBT: not applicable

vPvB: not applicable

3. Composition/Information of Ingredients

Chemical characterization:

Description:

mixture of poly- and difunctional methacrylates, barium glass filler, fumed silica,

photoinitiator, accelerator, stabilizer

Hazardous components: none

4. First-aid measures

General information: no special measures required

after skin contact: wash with plenty of water and soap

after eye contact: rinse with plenty of water and consult a doctor

after swallowing: If symptoms persist consult a doctor

5. Fire fighting measures

Extinguishing media: CO2, water

Protective equipment: no special measures required

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| 6. Accidental release measures | | |
| Personal precautions: not required Environmental precautions: Do not allow Methods for cleaning up: pick up mech Additional information: none | w to enter drains/surface water/ ground-water anically | |
| 7. Handling and storage | | |
| or upon their instructions. Information for safe handling: For denta Recommendation for fire and explosion Storage: store at a dry place, protected | ners: Store only in the original containers. ducts : Keep away from foodstuffs. | |
| 8. Exposure controls/personal prote | ction | |
| Components with limits of values to be a The product does not contain any releve have to be monitored at the workplace Additional information: The lists valid due Personal protective equipment: General measures of protection and hy Respiratory protection: not required Protection of hands: not required Eye protection: not absolute required | rant quantities of materials with critical values that ring the making were used as basis. | |
| 9. Physical and chemical properties | ; | |
| Appearance: | | |
| Form: | paste | |
| Color: | tooth colored | |
| Odor: | odorlessodorless | |
| | Value Unit Method | |
| Information on change in the physical s | | |
| Melting point/melting range: | n.a. °C | |
| Boiling point/boiling range: | n.a. °C | |
| Flash point: | n.d. °C | |
| Autoignition temperature: | n.d. | |
| Danger of explosion: | none | |
| Density: | 1,90 (20°C) g/cm3 | |
| Vapor pressure: | n.a. mbar | |
| Viscosity: | paste | |
| pH: | neutral | |
| Solubility in/miscibility with: | Partially soluble in toluene, silicone oil | |
| Water: | insoluble | |
| Content of solvents: | none | |
| Organic solvents: | | |
| Water: | | |
| Content of solids: | n.a. | |

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10. Stability and reactivity

Conditions to avoid:

heat, direct sunlight, peroxides, metal powders, strong oxidizers, free radical initiators

Hazardous decomposition products: none under normal conditions of storage and use

11. Toxicological information

Acute toxicity:

Primary irritation:

skin: irritating

eye: irritating

Sensitization of product: not observed

Additional toxicological information:

Allergic reation to methacrylate by chronic exposure to product 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.

12. Ecological information

General information: Avoid transfer into environment

Classification of water endangerment: -

13. Disposal considerations

Product:

Recommendation: Small quantities can be disposed of with household waste.

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: -

Maritime transport: IMDG-Code: -

Air transport ICAO-TI/IATA-DGR: -

15. Regulatory information

Classification according to EC-guidelines:

The product is a medical device according to EC-directive 93/42 EEC. The product must

not be labelled according to EC-regulations or the corresponding national regulations.

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.

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