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

Date of issue: 08.01.2014 Version: 6

Printing date: 10.01.2014

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

Product Identifier

Trade name: HeyTec Temp 4:1

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 polyfunctional acrylates and methacrylates, unsaturated esters and malonyl urea derivatives

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 to enter drains/surface water/ ground-water

Methods for cleaning up: wipe out with absorbent material

Additional information: none

7. Handling and storage

Handling: This product should only be supplied or handled to dentists, dental technicians

or upon their instructions.

Information for safe handling: For dental use only. No special measures required. **Recommendation for fire and explosion protection**: No special measures required

Storage: store at a dry place, storage temperature <25°C

Requirements at storerooms and containers: Store only in the original containers. **Requirements for storage with other products**: Keep away from foodstuffs.

Further information on storage conditions: none

8. Exposure controls/personal protection

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

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace

Additional information: The lists valid during the making were used as basis.

Personal protective equipment:

General measures of protection and hygiene: normal hygienic measures

Respiratory protection: not required Protection of hands: not required Eye protection: not absolute required

9. Physical and chemical properties

Appearance:

Form: paste

Color: tooth colored
Odor: nearly odorless

Value Unit Method

Information on change in the physical state

Autoignition temperature:n.d.Danger of explosion:none

Density: 1,50 (20°C) g/cm3

Vapor pressure: n.a. mbar

Viscosity: paste pt: neutral

Solubility in/miscibility with:Partially soluble in toluene

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: repeated and prolonged exposure may cause skin irritations

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.