



**Safety data sheet
according to 1907/2006/EC, Article 31**

Printing date 12.07.2022

Version number 3

Revision: 12.07.2022

SECTION 1: Identification of the substance/mixture and of the company/undertaking

· **1.1 Product identifier**

· Trade name: **Meliodent Rapid Repair Powder**

· **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.

· Application of the substance / the mixture *Manufacture of dental prosthesis*

· **1.3 Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**

Kulzer GmbH

Leipziger Straße 2, 63450 Hanau (Germany)

Tel.: +49 (0)800 4372522

· Informing department: E-Mail: msds@kulzer-dental.com

· **1.4 Emergency telephone number: Emergency CONTACT (24-Hour-Number): +49 (0)6132-84463**

SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**

· Classification according to Regulation (EC) No 1272/2008

The product is not classified, according to the GB CLP regulation.

· **2.2 Label elements**

· Labelling according to Regulation (EC) No 1272/2008 *Void*

· Hazard pictograms *Void*

· Signal word *Void*

· Hazard statements *Void*

· **2.3 Other hazards -**

· Results of PBT and vPvB assessment

· PBT: *Not applicable.*

· vPvB: *Not applicable.*

SECTION 3: Composition/information on ingredients

· **3.2 Mixtures**

· Description: *Product based on methacrylate copolymers*

· Dangerous components: *Void*

· Additional information *For the wording of the listed hazard phrases refer to section 16.*

SECTION 4: First aid measures

· **4.1 Description of first aid measures**

· General information *No special measures required.*

· After inhalation *Supply fresh air; consult doctor in case of symptoms.*

· After skin contact *Instantly wash with water and soap and rinse thoroughly.*

· After eye contact *Rinse opened eye for several minutes under running water.*

· After swallowing

Rinse out mouth and then drink plenty of water.

In case of persistent symptoms consult doctor.

· **4.2 Most important symptoms and effects, both acute and delayed**

No further relevant information available.

· **4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

GB

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SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
 - **Suitable extinguishing agents** void
- **5.2 Special hazards arising from the substance or mixture**
No further relevant information available.
- **5.3 Advice for firefighters**
 - **Protective equipment:** No special measures required.
 - **Additional information** -

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** No special measures required.
- **6.3 Methods and material for containment and cleaning up:** Collect mechanically.
- **6.4 Reference to other sections**
No dangerous materials are released.
See Section 8 for information on personal protection equipment.
-

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** No special measures required.
 - **Information about protection against explosions and fires:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
 - **Storage**
 - **Requirements to be met by storerooms and containers:** No special requirements.
 - **Information about storage in one common storage facility:** Not required.
 - **Further information about storage conditions:** Store cool (not above 25 °C).
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
 - **Components with critical values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
Not required.
 - **Additional information:** The lists that were valid during the compilation were used as basis.
- **8.2 Exposure controls**
 - **Appropriate engineering controls** No further data; see item 7.
 - **Individual protection measures, such as personal protective equipment**
 - **General protective and hygienic measures**
The usual precautionary measures should be adhered to in handling the chemicals.
 - **Breathing equipment:** Not required.
 - **Hand protection**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
Check protective gloves prior to each use for their proper condition.
recommended

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- **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:**
Butyl rubber, BR
Nitrile rubber, NBR
- **Eye/face protection** not absolutely necessary
- **Body protection:** Light weight protective clothing

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

- **Physical state** Solid.
- **Colour:** According to product specification
- **Smell:** Odourless
 - **Odour threshold:** Not determined.
- **Melting point/freezing point:** Not determined
- **Boiling point or initial boiling point and boiling range** Not determined
- **Flammability** Not determined.
- **Lower and upper explosion limit**
 - **Lower:** Not determined.
 - **Upper:** Not determined.
- **Flash point:** Not applicable
- **Ignition temperature:** 400 °C
- **Decomposition temperature:** Not determined.

· **SADT**

- **pH** Not applicable.
- **Viscosity:**
 - **Kinematic viscosity** Not applicable.
 - **dynamic:** Not applicable.
- **Solubility**
 - **Water:** Insoluble
- **Partition coefficient n-octanol/water (log value)** Not determined.
- **Steam pressure:** Not applicable.
- **Density and/or relative density**
 - **Density at 20 °C** 0 g/cm³
 - **Relative density** Not determined.
 - **Vapour density** Not applicable.

· **9.2 Other information**

No further relevant information available.

- **Appearance:**
- **Form:** Powder

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· Important information on protection of health and environment, and on safety.

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| · Self-inflammability: | Product is not selfigniting. |
| · Explosive properties: | Product is not explosive. However, formation of explosive powder/air mixtures is possible. |
| · Solvent content: | |
| · Solids content: | 100.0 % |
| · Change in condition | |
| · Evaporation rate | Not applicable. |

· Information with regard to physical hazard classes

- | | |
|--|------|
| · Explosives | Void |
| · Flammable gases | Void |
| · Aerosols | Void |
| · Oxidising gases | Void |
| · Gases under pressure | Void |
| · Flammable liquids | Void |
| · Flammable solids | Void |
| · Self-reactive substances and mixtures | Void |
| · Pyrophoric liquids | Void |
| · Pyrophoric solids | Void |
| · Self-heating substances and mixtures | Void |
| · Substances and mixtures, which emit flammable gases in contact with water | Void |
| · Oxidising liquids | Void |
| · Oxidising solids | Void |
| · Organic peroxides | Void |
| · Corrosive to metals | Void |
| · Desensitised explosives | Void |

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
 - **Conditions to be avoided:** No decomposition if used and stored according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** None
 - **Additional information:** -

SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
 - **Acute toxicity** Based on available data, the classification criteria are not met.
 - **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
 - **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
 - **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
 - **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
 - **Carcinogenicity** Based on available data, the classification criteria are not met.
 - **Reproductive toxicity** Based on available data, the classification criteria are not met.
 - **STOT-single exposure** Based on available data, the classification criteria are not met.

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- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.
- **11.2 Information on other hazards**

· **Endocrine disrupting properties**

None of the ingredients is listed.

SECTION 12: Ecological information

- **12.1 Toxicity**
 - **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**
For information on endocrine disrupting properties see section 11.
- **12.7 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
 - **Recommendation**
Small quantities can be polymerized with the matching system component(s) and the cured solid material can be disposed of with the regular garbage. Larger quantities must be disposed of following the regulations of the local authorities.
- **Uncleaned packagings:**
 - **Recommendation:** Packaging can be reused or recycled after cleaning.

SECTION 14: Transport information

- | | |
|---|-----------------|
| · 14.1 UN number or ID number
· ADR, ADN, IMDG, IATA | Void |
| · 14.2 UN proper shipping name
· ADR, ADN, IMDG, IATA | Void |
| · 14.3 Transport hazard class(es)
· ADR, ADN, IMDG, IATA
· Class | Void |
| · 14.4 Packing group
· ADR, IMDG, IATA | Void |
| · 14.5 Environmental hazards:
· Marine pollutant: | No |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Maritime transport in bulk according to IMO instruments | Not applicable. |

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- | | |
|--|------|
| · Transport/Additional information: | - |
| · UN "Model Regulation": | Void |

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
 - **Directive 2012/18/EU**
 - **Water hazard class:** Generally not hazardous for water.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Abbreviations and acronyms:**

- RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
- IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)
- ICAO: International Civil Aviation Organisation
- ICAO-TI: Technical Instructions by the "International Civil Aviation Organisation" (ICAO)
- SADT: Self Accelerating Decomposition Temperature
- ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
- IMDG: International Maritime Code for Dangerous Goods
- IATA: International Air Transport Association
- GHS: Globally Harmonised System of Classification and Labelling of Chemicals
- EINECS: European Inventory of Existing Commercial Chemical Substances
- ELINCS: European List of Notified Chemical Substances
- CAS: Chemical Abstracts Service (division of the American Chemical Society)
- PBT: Persistent, Bioaccumulative and Toxic
- vPvB: very Persistent and very Bioaccumulative

- *** Data compared to the previous version altered.**