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

Printing date 12.07.2022

Version number 3

Revision: 12.07.2022

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 prothesis				
 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 43725			
• Informing department: E-Mail: msds@kulzer-dental.com • 1.4 Emergency telephone number: Emergency CONTACT (24)	-Hour-Number): +49 (0)6132-8446			
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 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. 	1			
SECTION 3: Composition/information on ingredier	nts			
• 3.2 Mixtures • Description: Product based on methacrylate copolymers				
 Dangerous components: Void Additional information For the wording of the listed hazard p 	ohrases refer to section 16.			
SECTION 4: First aid measures				

- 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.

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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 trough 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 neccessary
- · Body protection: Light weight protective clothing

SECTION 9: Physical and chemical properties

• 9.1 Information on basic physical and chemi	cal properties
General Information Physical state	Solid.
· Colour:	According to product specification
· Smell:	Odourless
Odour threshold:	Not determined.
	Not determined
• Melting point/freezing point:	
Boiling point or initial boiling point an	
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 (le	
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.
Particle characteristics	See item 3.
Particle characteristics	See item 3.
• 9.2 Other information A	lo further relevant information available.
· Appearance:	
Form:	Powder
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· Important information on protection of		
health and environment, and on safety.		
· Self-inflammability:	Product is not selfigniting.	
 Explosive properties: 	Product is not explosive. However, formation	
	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	
	Void	
· Pyrophoric liquids	Void	
Pyrophoric solids	Void	
Self-heating substances and mixtures	VOIU	
Substances and mixtures, which emit	Void	
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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(Contd. of page 4) • 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.

· European waste catalogue

18 01 06 chemicals consisting of or containing dangerous substances

Uncleaned packagings:

Recommendation: Packaging can be reused or recycled after cleaning.

14.1 UN number or ID number	Void	
· 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	



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Not applicable.

Not applicable.

Void

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· 14.6 Special precautions for user

· 14.7 Maritime transport in bulk according to

IMO instruments

· Transport/Additional information:

• UN "Model Regulation":

SECTION 15: Regulatory information

 \cdot 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II

None of the ingredients is listed.

· REGULATION (EU) 2019/1148

Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

no information available

· Annex II - REPORTABLE EXPLOSIVES PRECURSORS

no information available

Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

None of the ingredients is listed.

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.

- Date of previous version: 12.07.2022
- Version number of previous version: 2
- 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.