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

Printing date 07.07.2022

Version number 3

Revision: 04.07.2022

SECTION 1: Identification of the substance/m undertaking				
1.1 Product identifier				
• Trade name: Paladent 20 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 	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 (2				
SECTION 2: Hazards identification				
• 2.1 Classification of the substance or mixture • Classification according to Regulation (EC) No 1272/200 The product is not classified, according to the CLP regulatio	08 n.			
 2.2 Label elements Labelling according to Regulation (EC) No 1272/2008 Vol Hazard pictograms Void Signal word Void Hazard statements Void 2.3 Other hazards - Results of PBT and vPvB assessment 	bid			
• PBT: Not applicable. • vPvB: Not applicable.				
SECTION 3: Composition/information on ingredie	ents			
• 3.2 Mixtures • Description: Product based on methacrylate copolymers				
 Dangerous components: Void Additional information For the wording of the listed hazard 	d 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.

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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 necessary if room is well-ventilated.

Hand protection

Check protective gloves prior to each use for their proper condition.

- recommended
 - 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.

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(Contd. of page 2) 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 Protective goggles are recommended. · 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: Pink Odourless · Smell: 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. Not applicable 400.0 °C · Flash point: Ignition temperature: Decomposition temperature: Not determined. SADT pН Not applicable. Viscosity: Kinematic viscosity Not applicable. · dynamic: Not applicable. Solubility Water: Insoluble · Partition coefficient n-octanol/water (log Not determined. value) · Steam pressure: Not applicable. · Density and/or relative density 0 g/cm³ · Density at 20 °C Not determined. · Relative density · Settled apparent density at 20 °C 700 kg/m3 · Vapour density Not applicable. · Particle characteristics See item 3. No further relevant information available. · 9.2 Other information Appearance: Form: Powder · 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 of explosive powder/air mixtures is possible. (Contd. on page 4)



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	1	Contd. of
· 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 lĭquids	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.
- 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.

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· 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

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

European waste catalogue

18 01 06* chemicals consisting of or containing hazardous substances

Uncleaned packagings:

Recommendation: Packaging can be reused or recycled after cleaning.

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 accordi IMO instruments	ng to 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

REGULATION (EU) 2019/1148

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: 16.05.2022
- Version number of previous version: 2
- Abbreviations and acronyms:

SADT: Self Accelerating Decomposition Temperature ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement ADK: Accord relating at transport international des matchandises dangere 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.