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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/mixture and of the company/ 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 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 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.



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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.

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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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· 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
· Smell: Odourless

Odour threshold:
Not determined.
Not determined

· Boiling point or initial boiling point and

boiling range Not determined Not determined.

Lower and upper explosion limit

Lower:
Upper:
Not determined.
Not determined.
Flash point:
Not applicable
400.0 °C

<u>Decomposition temperature:</u> Not determined.

SADT

· **pH** Not applicable.

· Viscosity:

* Kinematic viscosity Not applicable.

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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
Settled apparent density at 20 °C
Vapour density

Not determined.
700 kg/m3
Not applicable.

• **9.2 Other information** No further relevant information available.

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.

Solvent content: 100.0 %

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Change in condition	A	
· 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.
 - · 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.

- 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.	
14.7 Maritime transport in bulk accordi IMO instruments Transport/Additional information:		
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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:

SADT: Self Accelerating Decomposition Temperature

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement

ADR: Accord relatif at transport international des marchandises 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.