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Revision: 02.08.2022

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

Printing date 02.08.2022

Version number 4 (replaces version 3)

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

- · 1.1 Product identifier
  - · Trade name: Paladent 20 liquid
- · 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

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

Skin Irrit. 2 H315 Causes skin irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction.

STOT SE 3 H335 May cause respiratory irritation.

· 2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the GB CLP regulation.

Hazard pictograms





GHS02 GHS07

- · Signal word Danger
- · Hazard-determining components of labelling:

methyl methacrylate

1,4-butandioldimethacrylate

· Hazard statements

H225 Highly flammable liquid and vapour.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H335 May cause respiratory irritation.

Precautionary statements

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition

sources. No smoking.

P260 Do not breathe mist/vapours/spray. P280 Wear protective gloves / eye protection.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

· 2.3 Other hazards -

Results of PBT and vPvB assessment

· PBT: Not applicable.

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· vPvB: Not applicable.

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#### **SECTION 3: Composition/information on ingredients**

- · 3.2 Mixtures
  - · Description: Product based on methacrylates

· Dangerous com	· Dangerous components:	
CAS: 80-62-6	methyl methacrylate	>90%
EINECS: 201-297-1	Flam. Liq. 2, H225 Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	
CAS: 2082-81-7	1,4-butandioldimethacrylate	<i>≥</i> 1- <i>≤</i> 5%
EINECS: 218-218-1	Skin Sens. 1B, H317	
CAS: 99-85-4	p-Mentha-1,4-diene	<0.25%
EINECS: 202-794-6	Flam. Liq. 3, H226	
	Repr. 2, H361	
	Aquatic Chronic 2, H411	

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
  - · After inhalation Supply fresh air; consult doctor in case of symptoms.
  - After skin contact

Instantly wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

· After eye contact

Rinse opened eye for several minutes under running water. Then consult doctor.

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.

#### SECTION 5: Firefighting measures

- 5.1 Extinguishing media
  - · Suitable extinguishing agents CO2, sand, extinguishing powder. Do not use water.
  - For safety reasons unsuitable extinguishing agents Water.
- · 5.2 Special hazards arising from the substance or mixture

Can form explosive gas-air mixtures.

Formation of toxic gases is possible during heating or in case of fire.

- 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 Wear protective equipment. Keep unprotected persons away. Avoid contact with eyes and skin.

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- 6.2 Environmental precautions: Prevent material from reaching sewage system, holes and cellars.
- · 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).

Do not flush with water or aqueous cleansing agents

Send for recovery or disposal in suitable containers.

6.4 Reference to other sections

See Section 13 for information on disposal.

See Section 8 for information on personal protection equipment.

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# SECTION 7: Handling and storage

- · 7.1 Precautions for safe handling Keep containers tightly sealed.
  - Information about protection against explosions and fires:

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

- · 7.2 Conditions for safe storage, including any incompatibilities
  - · Storage
    - · Requirements to be met by storerooms and containers: Store in cool location.
    - · Information about storage in one common storage facility: Not required.
    - · Further information about storage conditions:

Store cool (not above 25 °C).

Store in cool, dry conditions in well sealed containers.

· 7.3 Specific end use(s) No further relevant information available.

#### SECTION 8: Exposure controls/personal protection

· 8.1 Contr	ol parameters			
· Comp	onents with cri	itical values that require	monitoring at the workplace:	
80-62-6 m	nethyl methacry	ylate		
WEL (Great Britain) Short-term value: 416 mg/m³, 100 ppm Long-term value: 208 mg/m³, 50 ppm				
IOELV (E	IOELV (European Union) Short-term value: 100 ppm Long-term value: 50 ppm			
· DN	ELs			
80-62-6 m	nethyl methacry	ylate		
Oral	general popula	tion, long term, systemic	8.2 mg/Kg (not defined)	
Dermal		ial, long term, systemic tion, long term, systemic	13.67 mg/Kg/d (not defined) 8.2 mg/Kg/d (not defined)	

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Dermal	worker industrial, long term, systemic	13.67 mg/Kg/d (not defined)
	general population, long term, systemic	8.2 mg/Kg/d (not defined)
Inhalative	worker industrial, acute, local	416 mg/m3 (not defined)
	worker industrial, long term, systemic	348.4 mg/m3 (not defined)
	worker industrial, long term, local	208 mg/m3 (not defined)
	general population, acute, local	208 mg/m3 (not defined)
	general population, long term, systemic	74.3 mg/m3 (not defined)

2082-81-7	1.4-butandioldimethacrylate

Oral	general population, long term, systemic	2.5 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	4.2 mg/Kg/d (not defined)
	general population, long term, systemic	2.5 ma/Ka/d (not defined)

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Inhalative worker professional, long	g term, systemic 14.5 mg/m3 (not defined)
general population, long	term, systemic 4.3 mg/m3 (not defined)
· PNECs	
80-62-6 methyl methacrylate	
freshwater	0.94 mg/l (not defined)
marine water	0.094 mg/l (not defined)
sewage treatment plant	10 mg/l (not defined)
sediment, dry weight, freshwater	10.2 mg/Kg (not defined)
sediment, dry weight, marine water	r 0.102 mg/Kg (not defined)
soil, dry weight	1.48 mg/Kg (not defined)
2082-81-7 1,4-butandioldimethac	rylate
freshwater	0.043 mg/l (not defined)
marine water	0.004 mg/l (not defined)
sewage treatment plant	2 mg/l (not defined)
sediment, dry weight, freshwater	3.12 mg/Kg (not defined)
sediment, dry weight, marine water	r 0.312 mg/Kg (not defined)
soil, dry weight	0.573 mg/Kg (not defined)

<sup>·</sup> 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

Keep away from foodstuffs, beverages and food.

Instantly remove any soiled and impregnated garments.

Wash hands during breaks and at the end of the work.

Avoid contact with the eyes and skin.

#### · Breathing equipment:

Not neccessary with efficient local exhaust. If exposition to vapours is possible, use breathing protective mask (filter A).

#### · Hand protection

PVA gloves

If skin contact cannot be avoided, protective gloves are recommended to avoid possible sensitization.

Solvent resistant gloves

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.

#### · 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 Tightly sealed safety glasses.

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· Body protection: Light weight protective clothing

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# SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

General Information

· Physical state Fluid · Colour: Colourless · Smell: Ester-like

Odour threshold: Not determined.

-48 °C

· Melting point/freezing point: · Boiling point or initial boiling point and

boiling range 100 °C (80-62-6 methyl methacrylate)

· Flammability Not applicable.

· Lower and upper explosion limit

2.1 Vol % Lower: 12.5 Vol % · Upper:

· Flash point: 10 °C (80-62-6 methyl methacrylate)

Ignition temperature: 430.0 °C Not determined. Decomposition temperature:

Paladent 20 liquid > 60 °C

SADT

· pH Mixture is non-soluble (in water).

Viscosity:

Kinematic viscosity Not determined. · dynamic at 20 °C: 1 mPas

Solubility

Water at 20 °C: 15.9 q/l

Partition coefficient n-octanol/water (log

Not determined. value)

Steam pressure at 20 °C: 47 hPa

Density and/or relative density

Density at 20 °C 0.940 g/cm3 Relative density Not determined. · Vapour density Not determined.

· 9.2 Other information No further relevant information available.

Appearance:

Form: Liquid

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

· Self-inflammability: Product is not selfianiting.

Explosive properties: Product is not explosive. However, formation of

explosive air/vapour mixtures is possible.

Change in condition

Evaporation rate Not determined.

· Information with regard to physical hazard

classes

· Explosives Void Flammable gases Void · Aerosols Void · Oxidising gases Void

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· Gases under pressure	Void
· Flammable liquids	Highly flammable liquid and vapour.
· 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:

If stored longer than recommended and/or above recommended temperature, product may polymerize generating heat.

#### 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.

· LD/	· LD/LC50 values that are relevant for classification:		
80-62-6 m	ethyl met	hacrylate	
Oral	LD50	~7,900 mg/kg (rat)	
Dermal	LD50	>5,000 mg/kg (guinea pig) (OECD 402)	
Inhalative	LC50/4 h	29.8 mg/l (rat)	
2082-81-7	2082-81-7 1,4-butandioldimethacrylate		
Oral	LD50	10,066 mg/kg (rat) (OECD 401)	
99-85-4 p-	99-85-4 p-Mentha-1,4-diene		
Oral	LD50	>2,000 mg/kg (rat) (OECD 423)	
Dermal	LD50	>2,000 mg/kg (rat) (OECD 402)	

- Skin corrosion/irritation
  - Causes skin irritation.
- Serious eye damage/irritation Based on available data, the classification criteria are not met.
- Respiratory or skin sensitisation May cause an allergic skin reaction.
- 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.

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- · STOT-single exposure
- May cause respiratory irritation.
- · 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.

12.1 Toxicity	,
· Aquatic t	oxicity:
80-62-6 meth	nyl methacrylate
EC50/21d	49 mg/L (daphnia) (OECD 211)
EC50/48h	69 mg/l (daphnia) (EPA OTS 797.1300)
NOEC / 21d	37 mg/l (daphnia) (OECD 211)
ErC50 / 72 h	>110 mg/l (algae) (OECD 201)
NOEC / 72h	110 mg/l (algae) (OECD 201)
NOEC / 48h	48 mg/l (daphnia) (EPA OTS 797.1300)
EbC50 / 72h	>110 mg/l (algae) (OECD 201)
NOEC/ 35d	9.4 mg/L (fish) (OECD 210)
LC50/ 35d	33.7 mg/L (fish) (OECD 210)
2082-81-7 1,4	4-butandioldimethacrylate
EC50/21d	14.1 mg/L (daphnia) (OECD 211)
EC50/48h	32.5 mg/l (fish)
NOEC / 21d	5.09 mg/l (daphnia) (OECD 211)
ErC50 / 72 h	9.79 mg/l (algae) (OECD 201)
NOEC / 72h	2.11 mg/l (algae) (OECD 201)
NOEC / 48h	25 mg/l (fish)
ErC10/72h	4.35 mg/L (algae) (OECD 201)
99-85-4 р-Ме	entha-1,4-diene
EC50/72h	>10.82 mg/l (algae) (OECD 201)

EC50/72h	>10.82 mg/l (algae) (OECD 201)
EC50/48h	10.189 mg/l (daphnia) (OECD 202)
LC50/96h	2.792 mg/l (fish) (OECD 203)

#### · 12.2 Persistence and degradability

#### 80-62-6 methyl methacrylate

Biodegradation 94 % /14d (not defined) (OECD 301C)

#### 2082-81-7 1,4-butandioldimethacrylate

Biodegradation 84 % /28d (not defined) (OECD 310)

# 99-85-4 p-Mentha-1,4-diene

Biodegradation 27 % /28d (not defined) (OECD 301F; ISO 9408/ EEC 92/69/V, C.4-D)

- 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.

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· 12.6 Endocrine disrupting properties

For information on endocrine disrupting properties see section 11.

- · 12.7 Other adverse effects
  - · Additional ecological information:
    - · General notes:

Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.

### 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.

Disposal must be made according to official regulations.

- · Uncleaned packagings:
  - Recommendation:

Disposal must be made according to official regulations. Non contaminated packagings can be used for recycling.

14.1 UN number or ID number · ADR, IMDG, IATA	UN1247
14.2 UN proper shipping name ADR	1247 METHYL METHACRYLATE MONOMEI STABILIZED solution
· IMDG, IATA	METHYL METHACRYLATE MONOMER STABILIZED solution
14.3 Transport hazard class(es)	
ADR	
· Class · Label	3 (F1) Flammable liquids. 3
· IMDG, IATA	
· Class · Label	3 Flammable liquids. 3
14.4 Packing group ADR, IMDG, IATA	II



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14.5 Environmental hazards: Marine pollutant:	No
14.6 Special precautions for user	Warning: Flammable liquids.
Kemler Number:	339
· EMS Number:	F-E,S-D
Stowage Category	В
· Stowage Code	SW2 Clear of living quarters.
14.7 Maritime transport in bulk according to	0
IMO instruments	Not applicable.
· Transport/Additional information:	-
ADR	
Limited quantities (LQ)	1L
Excepted quantities (EQ)	Code: E2
	Maximum net quantity per inner packagin
	30 ml
	Maximum net quantity per outer packagin
<b>-</b>	500 ml
Transport category	2
· Tunnel restriction code	D/E
· IMDG	
· Limited quantities (LQ)	1L
Excepted quantities (EQ)	Code: E2
	Maximum net quantity per inner packagir
	30 ml
	Maximum net quantity per outer packagir 500 ml
· UN "Model Regulation":	UN 1247 METHYL METHACRYLAT

#### SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
  - Directive 2012/18/EU
    - · Qualifying quantity (tonnes) for the application of lower-tier requirements 5.000 t
    - Qualifying quantity (tonnes) for the application of upper-tier requirements 50.000 t
- 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.

. Relevant phrases

H225 Highly flammable liquid and vapour.

H226 Flammable liquid and vapour.

H315 Causes skin İrritation.

H317 May cause an allergic skin reaction.

H335 May cause respiratory irritation.

H361 Suspected of damaging fertility or the unborn child.

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H411 Toxic to aquatic life with long lasting effects. Abbreviations and acronyms:

SADT: Self Accelerating Decomposition Temperature SAPT: Self Accelerating Polymerisation Temperature

SAPT: Self Accelerating Polymerisation 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)
DNEL: Derived No-Effect Level (UK REACH)
PNEC: Predicted No-Effect Concentration (UK REACH)

PNEC: Predicted No-Effect Concentration (ÚK REACH)

PNEC: Predicted No-Effect Concentration (UK KI LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative Flam. Liq. 2: Flammable liquids – Category 2 Flam. Liq. 3: Flammable liquids – Category 3 Skin Irrit. 2: Skin corrosion/irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1 Skin Sens. 1B: Skin sensitisation – Category 1B

Repr. 2: Reproductive toxicity – Category 2 STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2 \* Data compared to the previous version altered.