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

Printing date 03.06.2017 Version number 3 Revision: 03.06.2017

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

- · 1.1 Product identifier
 - · Trade name: Paladur 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 CLP regulation.

· Hazard pictograms





GHS02 GHS07

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

methyl methacrylate

2-(2H-Benzotriázol-2-yl)-4-methylphenol

· 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/sparks/open flames/hot surfaces. - No smoking.

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

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

P370+P378 In case of fire: Use for extinction: CO2, sand, extinguishing powder.

P403+P233 Store in a well-ventilated place. Keep container tightly closed.

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· 2.3 Other hazards -

- · Results of PBT and vPvB assessment
 - · PBT: Not applicable. · vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

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

 Dangerous components: 		
CAS: 80-62-6 EINECS: 201-297-1 Reg.nr.: 01-2119452498-28-0000	methyl methacrylate Flam. Liq. 2, H225; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	> 90%
CAS: 2082-81-7 EINECS: 218-218-1 Reg.nr.: 02-2119849716-25	tetramethylene dimethacrylate Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	0-5%
CAS: 2440-22-4 Reg.nr.: 01-2119583811-34-0000 01-2119583811-34-0001	2-(2H-Benzotriazol-2-yl)-4-methylphenol Acute Tox. 3, H331; Aquatic Chronic 1, H410; Skin Sens. 1, H317	< 1%
CAS: 99-97-8 EINECS: 202-805-4	N,N-dimethyl-p-toluidine Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331; STOT RE 2, H373; Aquatic Chronic 3, H412	< 1%

[·] 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 If skin irritation continues, consult a doctor.
 - · 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.

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.

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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.
- 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.

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

- · Additional information about design of technical systems: No further data; see item 7.
- · 8.1 Control parameters
 - · Components with critical values that require monitoring at the workplace:

80-62-6 methyl methacrylate

OES () Short-term value: 416 mg/m³, 100 ppm

Long-term value: 208 mg/m³, 50 ppm

· DNELs

80-62-6 methyl methacrylate

Dermal worker industr., I.te., syst. 74.3 mg/Kg/d (human)

Inhalative worker industr., I.te., syst. 210 mg/m3 (human)

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2440.22	4.2./2U.Ba		(Contd. of page
2440-22-4 Oral		• /	-4-methylphenol 1.2 mg/Kg (nd)
	. ,		2.5 mg/Kg/d (nd)
Demiai			1.2 mg/Kg/d (nd)
Inhalative	J , , ,	lustr., l.te., syst.	
	PNECs	· · · · · ·	
80-62-6 n	nethyl meth	nacrylate	
freshwater 0.94 mg/l (aqua		0.94 mg/l (aqua	a)
2440-22-4	4 2-(2H-Ber	zotriazol-2-yl)-	-4-methylphenol
freshwater 0.1 mg/l (nd)		0.1 mg/l (nd)	
marine wa	ater	0.01 mg/l (nd)	
STP 1 mg/l (nd)		1 mg/l (nd)	
sedim., dw, fre.wat. 52.3 mg/Kg (no		52.3 mg/Kg (no	d)
sedim., dw, mar.wat. 5.23 mg/Kg (nd		5.23 mg/Kg (no	d)
soil,dw 11 mg/Kg (nd)		•	

[·] Additional information: The lists that were valid during the compilation were used as basis.

· 8.2 Exposure controls

· 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).

· Protection of hands:

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

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.

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· 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 protection: Tightly sealed safety glasses.
Body protection: Light weight protective clothing

SECTION 9: Physical and chemical properties

C_C TOTAL CT T THY COOK IN CORNE	620 TON 6.1 Thyorodi and chomical proportion		
 9.1 Information on basic physical and General Information Appearance: 			
Form:	Fluid		
· Colour:	Colourless		
· Smell:	Characteristic		
· Odour threshold:	Not determined.		
· pH-value:	Not determined.		
 Change in condition Melting point/Melting range: Boiling point/Boiling range: 	Not determined 100 °C		
· Flash point:	10 ℃		
· Inflammability (solid, gaseous)	Not applicable.		
· Ignition temperature:	430 °C		
 Decomposition temperature: 	Not determined.		
· Self-inflammability:	Product is not selfigniting.		
· Danger of explosion:	Product is not explosive. However, formation of explosive air/vapour mixtures is possible.		
 Critical values for explosion: Lower: Upper: 	2.1 Vol % 12.5 Vol %		
· Steam pressure at 20 °C:	47 hPa		
 Density at 20 °C Relative density 	0.950 g/cm³ Not determined.		
· Vapour density	Not determined.		
· Evaporation rate	Not determined. Not determined.		
Solubility in / Miscibility with Water:	Not miscible or difficult to mix		
· Partition coefficient (n-octanol/wate	er): Not determined.		
· Viscosity:			
· dynamic at 20 °C:	1 mPas		
· kinematic:	Not determined.		
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· Solvent content:

· Solids content: 1.0 %

• 9.2 Other information No further relevant information available.

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 toxicological effects
 - · Acute toxicity Based on available data, the classification criteria are not met.

· LD/l	· LD/LC50 values that are relevant for classification:				
80-62-6 m	80-62-6 methyl methacrylate				
Oral	LD50	>5000 mg/kg (rat)			
Dermal	LD50	>5000 mg/kg (rab)			
Inhalative	LC50/4 h	29.8 mg/l (rat)			
2082-81-7	2082-81-7 tetramethylene dimethacrylate				
Oral	LD50	10120 mg/kg (rat)			
2440-22-4	2-(2H-Bei	nzotriazol-2-yl)-4-methylphenol			
Oral	LD50	>10000 mg/kg (rat)			
Dermal	LD50	>2000 mg/kg (rat)			
99-97-8 N,N-dimethyl-p-toluidine					
Inhalative	LC50/4 h	1400 mg/l (rat)			

- · Primary irritant effect:
 - · 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.
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
 - · 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.

SECTION 12: Ecological information

· 12.1 Toxicity

· Aquatic toxicity:

2440-22-4 2-(2H-Benzotriazol-2-yl)-4-methylphenol

EC50/72h >100 mg/l (algae) LC50/96h >0.17 mg/l (fish)

99-97-8 N,N-dimethyl-p-toluidine

LC50/96h | 100 mg/l (fish)

- · 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.
 - · Additional ecological information:
 - · General notes:

Do not allow product to reach ground water, water bodies or sewage system. Danger to drinking water if even small quantities leak into soil.

- · 12.5 Results of PBT and vPvB assessment
 - · PBT: Not applicable.
 - · vPvB: Not applicable.
- · 12.6 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.

Śmall 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: Disposal must be made according to official regulations.

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14.1 UN-Number · ADR, IMDG, IATA	1247
14.2 UN proper shipping name · ADR	1247 METHYL METHACRYLATE MONOME STABILIZED, solution
· IMDG, IATA	METHYL METHACRYLATE MONOME STABILIZED, solution
14.3 Transport hazard class(es)	
· ADR	
· Class · Label	3 (F1) Flammable liquids. 3
· IMDG, IATA	
· Class	3 Flammable liquids.
· Label	3
· 14.4 Packing group · ADR, IMDG, IATA	II .
· 14.5 Environmental hazards: · Marine pollutant:	No
14.6 Special precautions for user	Warning: Flammable liquids.
· Kemler Number: · EMS Number:	339 F-E,S-D
14.7 Transport in bulk according to Annex Marpol and the IBC Code	II of Not applicable.
· Transport/Additional information:	-
UN "Model Regulation":	UN1247, METHYL METHACRYLAT MONOMER, STABILIZED, solution, 3, II

SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
 - REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

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· 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.

H301 Toxic if swallowed.

H311 Toxic in contact with skin.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H331 Toxic if inhaled.

H335 May cause respiratory irritation.

H373 May cause damage to organs through prolonged or repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.

H412 Harmful to aquatic life with long lasting effects.

Abbreviations and acronyms:

ADR: Accord européen sur le transport 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 (REACH)
PNEC: Predicted No-Effect Concentration (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative Flam. Liq. 2: Flammable liquids – Category 2 Acute Tox. 3: Acute toxicity – Category 3 Skin Irrit. 2: Skin corrosion/irritation – Category 2 Eye Irrit. 2: Serious eye damage/eye irritation – Category 2 Skin Sens. 1: Skin sensitisation – Category 1 STOT SE 3: Specific target organ toxicity (single exposure) – Category 3 STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2 Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1 Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3 * Data compared to the previous version altered

* Data compared to the previous version altered.