



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

Printing date 20.08.2020

Version number 3

Revision: 20.08.2020

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

· **1.1 Product identifier**

· Trade name: **Paladent RR 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 prosthesis

· **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.

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

· **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

tetramethylene dimethacrylate

2-(2H-Benzotriazol-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.

H412 Harmful to aquatic life with long lasting effects.

· **Precautionary statements**

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

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

P273 Avoid release to the environment.

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

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

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- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.

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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-XXXX	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 Sens. 1B, H317	≥1-≤5%
CAS: 2440-22-4 Reg.nr.: 01-2119583811-34-0000 01-2119583811-34-0001	2-(2H-Benzotriazol-2-yl)-4-methylphenol ----- Aquatic Chronic 1, H410 Skin Sens. 1, H317	≥0.25-<1%
CAS: 99-97-8 EINECS: 202-805-4 Reg.nr.: 01-2119956633-31-xxxx	N,N-dimethyl-p-toluidine ----- Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 2, H330 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**
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** Allergic reactions
- **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** -

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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.
- **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**

Please observe the additional instructions in the product's instructions for use.
Keep containers tightly sealed.
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
Ensure good interior ventilation, especially at floor level. (Fumes are heavier than air).

 - **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., l.te., syst. 74.3 mg/Kg/d (human)

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Inhalative	worker industr., l.te., syst.	210 mg/m ³ (human)
2440-22-4 2-(2H-Benzotriazol-2-yl)-4-methylphenol		
Oral	ge.pop., l.te, syst.	1.2 mg/Kg (nd)
Dermal	worker industr., l.te., syst.	2.5 mg/Kg/d (nd)
	ge.pop., l.te, syst.	1.2 mg/Kg/d (nd)
Inhalative	worker industr., l.te., syst.	1 mg/m ³ (nd)

· PNECs

80-62-6 methyl methacrylate

freshwater 0.94 mg/l (aqua)

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

freshwater 0.00026 mg/l (nd)
marine water 0.000026 mg/l (nd)
interm. wat. release 1 mg/l (nd)
STP 1 mg/l (nd)
sedim., dw, fre.wat. 0.136 mg/Kg (nd)
sedim., dw, mar.wat. 0.0136 mg/Kg (nd)
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 necessary 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.

· For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:

Butyl rubber, BR
Nitrile rubber, NBR

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- **Eye protection:** Tightly sealed safety glasses.
- **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**

· **Appearance:**

- **Form:** Fluid
- **Colour:** Colourless
- **Smell:** Characteristic
- **Odour threshold:** Not determined.

· **pH-value:** Not determined.

· **Change in condition**

- **Melting point/freezing point:** Not determined
- **Initial boiling point and boiling range:** 100 °C

· **Flash point:** 10 °C

· **Inflammability (solid, gaseous)** Not applicable.

· **Ignition temperature:** 430 °C

· **Decomposition temperature:** Not determined.

· **Self-inflammability:** Product is not selfigniting.

· **Explosive properties:** Product is not explosive. However, formation of explosive air/vapour mixtures is possible.

· **Critical values for explosion:**

- **Lower:** 2.1 Vol %
- **Upper:** 12.5 Vol %

· **Steam pressure at 20 °C:** 47 hPa

· **Density at 20 °C** 0.950 g/cm³

- **Relative density** Not determined.
- **Vapour density** Not determined.
- **Evaporation rate** Not determined.

· **Solubility in / Miscibility with**

· **Water:** Not miscible or difficult to mix

· **Partition coefficient: n-octanol/water:** Not determined.

· **Viscosity:**

- **dynamic at 20 °C:** 1 mPas
- **kinematic:** Not determined.

· **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.

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- **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/LC50 values that are relevant for classification:**

80-62-6 methyl methacrylate

Oral	LD50	~7,900 mg/kg (rat)
Dermal	LD50	>5,000 mg/kg (rab) (OECD 402)
Inhalative	LC50/4 h	29.8 mg/l (rat)

2082-81-7 tetramethylene dimethacrylate

Oral	LD50	10,066 mg/kg (rat) (OECD 401)
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2440-22-4 2-(2H-Benzotriazol-2-yl)-4-methylphenol

Oral	LD50	>10,000 mg/kg (rat) (OECD 423)
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99-97-8 N,N-dimethyl-p-toluidine

Oral	LD50	139 mg/kg (rat)
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- **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 (carcinogenicity, 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.
- **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:**

80-62-6 methyl methacrylate

EC50/48h	69 mg/l (daphnia)
LC50/96h	191 mg/l (fish)

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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.
Disposal must be made according to official regulations.
 - **European waste catalogue**

18 01 06* | chemicals consisting of or containing hazardous substances
 - **Uncleaned packagings:**
 - **Recommendation:**

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

SECTION 14: Transport information

- **14.1 UN-Number**
 - **ADR, IMDG, IATA** 1247
- **14.2 UN proper shipping name**
 - **ADR** 1247 METHYL METHACRYLATE MONOMER, STABILIZED, solution
 - **IMDG, IATA** METHYL METHACRYLATE MONOMER, STABILIZED, solution
- **14.3 Transport hazard class(es)**
 - **ADR**

 - **Class** 3 (F1) Flammable liquids.

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· Label	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 · Kemler Number: · EMS Number:	Warning: Flammable liquids. 339 F-E,S-D
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	-
· UN "Model Regulation":	UN1247, METHYL METHACRYLATE 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
- 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.

H330 Fatal 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

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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
vPvB: very Persistent and very Bioaccumulative
Flam. Liq. 2: Flammable liquids – Category 2
Acute Tox. 3: Acute toxicity - oral – Category 3
Acute Tox. 2: Acute toxicity - inhalation – Category 2
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Skin Sens. 1: Skin sensitisation – Category 1
Skin Sens. 1B: Skin sensitisation – Category 1B
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.**

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