



**Safety data sheet
according to UK REACH**

Printing date 15.05.2025

Version number 4 (replaces version 3)

Revision: 15.05.2025

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

· **1.1 Product identifier**

· Trade name: **Paladon 65 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

Tetramethylene dimethacrylate

· **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 dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves / eye protection.

P280 Wear protective clothing.

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.

SECTION 3: Composition/information on ingredients

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

· **Dangerous components:**

CAS: 80-62-6 EINECS: 201-297-1 Index number: 607-035-00-6	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	Tetramethylene dimethacrylate Skin Sens. 1B, H317	≥1-≤5%
CAS: 99-85-4 EINECS: 202-794-6	p-Mentha-1,4-diene Flam. Liq. 3, H226 Repr. 2, H361 Aquatic Chronic 2, H411	<0.25%

- **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.
- **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.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

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· **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.
- **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.
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

· **8.1 Control parameters**

· **Components with critical values that require monitoring at the workplace:**

80-62-6 methyl methacrylate

WEL (Great Britain)	Short-term value: 416 mg/m ³ , 100 ppm Long-term value: 208 mg/m ³ , 50 ppm
IOELV (European Union)	Short-term value: 100 ppm Long-term value: 50 ppm

· **DNELs**

80-62-6 methyl methacrylate

Oral	general population, long term, systemic	8.2 mg/Kg (not defined)
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<i>Dermal</i>	<i>worker industrial, long term, systemic</i>	13.67 mg/Kg/d (not defined)
	<i>general population, long term, systemic</i>	8.2 mg/Kg/d (not defined)
<i>Inhalative</i>	<i>worker industrial, acute, local</i>	416 mg/m ³ (not defined)
	<i>worker industrial, long term, systemic</i>	348.4 mg/m ³ (not defined)
	<i>worker industrial, long term, local</i>	208 mg/m ³ (not defined)
	<i>general population, acute, local</i>	208 mg/m ³ (not defined)
	<i>general population, long term, systemic</i>	74.3 mg/m ³ (not defined)

2082-81-7 Tetramethylene dimethacrylate

<i>Oral</i>	<i>general population, long term, systemic</i>	2.5 mg/Kg (not defined)
<i>Dermal</i>	<i>worker industrial, long term, systemic</i>	4.2 mg/Kg/d (not defined)
	<i>general population, long term, systemic</i>	2.5 mg/Kg/d (not defined)
<i>Inhalative</i>	<i>worker professional, long term, systemic</i>	14.5 mg/m ³ (not defined)
	<i>general population, long term, systemic</i>	4.3 mg/m ³ (not defined)

· PNECs

80-62-6 methyl methacrylate

<i>freshwater</i>	0.94 mg/l (not defined)
<i>marine water</i>	0.094 mg/l (not defined)
<i>sewage treatment plant</i>	10 mg/l (not defined)
<i>sediment, dry weight, freshwater</i>	10.2 mg/Kg (not defined)
<i>sediment, dry weight, marine water</i>	0.102 mg/Kg (not defined)
<i>soil, dry weight</i>	1.48 mg/Kg (not defined)

2082-81-7 Tetramethylene dimethacrylate

<i>freshwater</i>	0.043 mg/l (not defined)
<i>marine water</i>	0.004 mg/l (not defined)
<i>sewage treatment plant</i>	2 mg/l (not defined)
<i>sediment, dry weight, freshwater</i>	3.12 mg/Kg (not defined)
<i>sediment, dry weight, marine water</i>	0.312 mg/Kg (not defined)
<i>soil, dry weight</i>	0.573 mg/Kg (not defined)

· 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 section 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 necessary with efficient local exhaust. If exposition to vapours is possible, use breathing protective mask (filter A).

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· **Hand protection**

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 through 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.

· **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**

Liquid

· **Colour:**

Colourless

· **Smell:**

Ester-like

· **Odour threshold:**

Not determined.

· **Melting point/freezing point:**

-48 °C

· **Boiling point or initial boiling point and boiling range**

100.3 °C (80-62-6 methyl methacrylate)

· **Flammability**

Not applicable.

· **Lower and upper explosion limit**

· **Lower:**

2.1 Vol %

· **Upper:**

12.5 Vol %

· **Flash point:**

11.5 °C (80-62-6 methyl methacrylate)

· **Auto-ignition temperature:**

430 °C

· **Decomposition temperature:**

Not determined.

· **SADT**

· **pH**

Mixture is non-soluble (in water).

· **Viscosity:**

· **Kinematic viscosity**

Not determined.

· **dynamic at 20 °C:**

1 mPas

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<ul style="list-style-type: none">· Solubility<ul style="list-style-type: none">· Water: Not miscible or difficult to mix· Partition coefficient n-octanol/water (log value) Not determined.· Steam pressure at 20 °C: 47 hPa· Density and/or relative density<ul style="list-style-type: none">· Density at 20 °C 0.940 g/cm³· Relative density Not determined.· Vapour density Not determined.	
<ul style="list-style-type: none">· 9.2 Other information No further relevant information available.· Appearance:<ul style="list-style-type: none">· Form: Fluid· Important information on protection of health and environment, and on safety.<ul style="list-style-type: none">· Self-inflammability: Product is not selfigniting.· Explosive properties: Product is not explosive. However, formation of explosive air/vapour mixtures is possible.· Change in condition<ul style="list-style-type: none">· Evaporation rate Not determined.	
<ul style="list-style-type: none">· Information with regard to physical hazard classes<ul style="list-style-type: none">· Explosives Void· Flammable gases Void· Aerosols Void· Oxidising gases Void· 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.

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- **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/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 (guinea pig) (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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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)

- **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.
- **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.

- **11.2 Information on other hazards**

· **Endocrine disrupting properties**

None of the ingredients is listed.

SECTION 12: Ecological information

- **12.1 Toxicity**

· **Aquatic toxicity:**

80-62-6 methyl methacrylate

EC50/21d	49 mg/L (daphnia) (OECD 211)
EC50/48h	69 mg/l (daphnia) (EPA OTS 797.1300)

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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 Tetramethylene dimethacrylate

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 p-Mentha-1,4-diene

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)
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2082-81-7 Tetramethylene dimethacrylate

Biodegradation	84 % /28d (not defined) (OECD 310)
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99-85-4 p-Mentha-1,4-diene

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

The product does not contain substances with endocrine disrupting properties.

· **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.

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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.

SECTION 14: Transport information

· **14.1 UN number or ID number**

· **ADR, IMDG, IATA**

UN1247

· **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.

· **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:**

Warning: Flammable liquids.

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· EMS Number:	F-E,S-D
· Stowage Category	B
· Stowage Code	SW2 Clear of living quarters.
· 14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
· Transport/Additional information:	-
· ADR	
· Limited quantities (LQ)	1L
· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 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 packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· UN "Model Regulation":	UN 1247 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**

· **Poisons Act**

· **Regulated explosives precursors**

None of the ingredients is listed.

· **Regulated poisons**

None of the ingredients is listed.

· **Reportable explosives precursors**

None of the ingredients is listed.

· **Reportable poisons**

None of the ingredients is listed.

· **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

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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.

H226 Flammable liquid and vapour.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H335 May cause respiratory irritation.

H361 Suspected of damaging fertility or the unborn child.

H411 Toxic to aquatic life with long lasting effects.

· **Abbreviations and acronyms:**

SADT: Self Accelerating Decomposition 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)

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.**