



**Safety data sheet
according to UK REACH**

Printing date 18.03.2025

Version number 5 (replaces version 4)

Revision: 13.03.2025

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

· **1.1 Product identifier**

· Trade name: **Palavit G 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.

Carc. 1B H350 May cause cancer.

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 GHS08

· **Signal word** Danger

· **Hazard-determining components of labelling:**

methyl methacrylate

N,N-dimethyl-p-toluidine

· **Hazard statements**

H225 Highly flammable liquid and vapour.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H350 May cause cancer.

H335 May cause respiratory irritation.

· **Precautionary statements**

P101 If medical advice is needed, have product container or label at hand.

P201 Obtain special instructions before use.

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

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P280 Wear protective gloves / eye protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P308+P313 IF exposed or concerned: Get medical advice/attention.

P403+P235 Store in a well-ventilated place. Keep cool.

· **Additional information:**

Restricted to professional users.

· **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:** -

· **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: 99-97-8 EINECS: 202-805-4 Index number: 612-056-00-9 Reg.nr.: 01-2119937766-23-xxxx	N,N-dimethyl-p-toluidine Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 2, H330 Carc. 1B, H350; Repr. 2, H361; STOT RE 2, H373 Skin Sens. 1, H317 Aquatic Chronic 3, H412 ATE: LD50 oral: 139 mg/kg LC50/4 h inhalative: 0.05 mg/l	≥2.5-<3%

· **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**

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

Personal protection for the First Aider.

· **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 or rash occurs: Get medical advice/attention.

· **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.

Seek medical treatment.

· **Information for doctor** Product based on methacrylates

· **4.2 Most important symptoms and effects, both acute and delayed Allergic reactions**

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- **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** 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.
 - Can be released in case of fire
 - Carbon dioxide (CO₂)
 - Carbon monoxide (CO)
 - Formation of toxic gases is possible during heating or in case of fire.
- **5.3 Advice for firefighters**
 - **Protective equipment:**
 - Wear self-contained breathing apparatus.
 - (EN 133)
 - Put on breathing apparatus.

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.
 - Keep away from ignition sources
- **6.2 Environmental precautions:**
 - Prevent material from reaching sewage system, holes and cellars.
 - Do not allow to enter drainage system, surface or ground water.
 - Keep dirty washing water for appropriate disposal.
- **6.3 Methods and material for containment and cleaning up:**
 - Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).
 - Dispose of the material collected according to regulations.
 - Send for recovery or disposal in suitable containers.
- **6.4 Reference to other sections**
 - See Section 7 for information on safe handling
 - See Section 8 for information on personal protection equipment.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
 - Keep containers tightly sealed.
 - Avoid contact with eyes and skin.
 - Ensure good ventilation/exhaustion at the workplace.
 - Keep away from heat and direct sunlight.
 - Prevent formation of aerosols.
 - Ensure good interior ventilation, especially at floor level. (Fumes are heavier than air).

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- **Information about protection against explosions and fires:**
 - Keep ignition sources away - Do not smoke.
 - Fumes can combine with air to form an explosive mixture.
 - Use explosion-proof apparatus / fittings and spark-proof tools.
 - Do not spray on flames or red-hot objects.
 - Avoid UV radiation/sunlight.
 - Protect from heat.
 - Protect against electrostatic charges.
- **Handling**
 - do not mix with organic peroxides
 - Radical initiator
 - reducing agent
 - Strong bases
 - Strong oxidizers
 - Strong acids
- **7.2 Conditions for safe storage, including any incompatibilities**
 - **Storage**
 - **Requirements to be met by storerooms and containers:**
 - Store in cool location.
 - Keep away from heat.
 - Protect from the effects of light.
 - **Information about storage in one common storage facility:** Store away from foodstuffs.
 - **Further information about storage conditions:**
 - Store in cool, dry conditions in well sealed containers.
 - Protect from heat and direct sunlight.
 - **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)
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/m ³ (not defined)
	worker industrial, long term, systemic	348.4 mg/m ³ (not defined)
	worker industrial, long term, local	208 mg/m ³ (not defined)

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	general population, acute, local	208 mg/m3 (not defined)
	general population, long term, systemic	74.3 mg/m3 (not defined)
99-97-8 N,N-dimethyl-p-toluidine		
Oral	general population, long term, systemic	0.02 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	0.624 mg/Kg/d (not defined)
	general population, long term, systemic	0.223 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, systemic	0.128 mg/m3 (not defined)
	general population, long term, systemic	0.0227 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		0.102 mg/Kg (not defined)
soil, dry weight		1.48 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.

Do not eat or drink while working.

The usual precautionary measures should be adhered to in handling the chemicals.

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).

· **Hand protection**

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

chemical protection gloves are suitable, which are tested according to EN 374

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.

Check protective gloves prior to each use for their proper condition.

· **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**
For the mixture of chemicals mentioned below the penetration time has to be at least 30 minutes (Permeation according to EN 16523-1:2015: Level 2).
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:** Protective work clothing.

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

- | | |
|---|--------------------------------------|
| · Physical state | Liquid |
| · Colour: | Colourless |
| · Smell: | Characteristic |
| · Odour threshold: | Not determined. |
| · Melting point/freezing point: | Not determined |
| · Boiling point or initial boiling point and boiling range | 100 °C (80-62-6 methyl methacrylate) |
| · Flammability | Not applicable. |
| · Lower and upper explosion limit | |
| · Lower: | Not determined. |
| · Upper: | Not determined. |
| · Flash point: | 10 °C (80-62-6 methyl methacrylate) |
| · Auto-ignition temperature: | 435 °C (80-62-6 methyl methacrylate) |
| · Decomposition temperature: | Not determined. |

· **SADT**

- | | |
|--|---|
| · pH | Mixture is non-soluble (in water).
Not determined. |
| · Viscosity: | |
| · Kinematic viscosity | Not determined. |
| · dynamic: | Not determined. |
| · Solubility | |
| · Water: | Not miscible or difficult to mix |
| · Partition coefficient n-octanol/water (log value) | Not determined. |
| · Steam pressure at 20 °C: | 37 hPa (80-62-6 methyl methacrylate) |
| · Density and/or relative density | |
| · Density at 20 °C | 0.94 g/cm ³ |
| · Relative density | Not determined. |
| · Vapour density | Not determined. |

· **9.2 Other information**

No further relevant information available.

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· Appearance:	
· Form:	Fluid
· 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 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
· 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 according to specifications.
- **10.3 Possibility of hazardous reactions** Exothermic polymerisation
- **10.4 Conditions to avoid** Heat, flames and sparks.
- **10.5 Incompatible materials:**
 - organic peroxides
 - Radical initiator
 - reducing agent
 - Strong bases
 - Strong oxidizers
 - Strong acids
- **10.6 Hazardous decomposition products:** None

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· **Additional information:** -

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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)

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

Oral	LD50	139 mg/kg (ATE) 139 mg/kg (rat)
Dermal	LD50	>2,000 mg/kg (rab) (OECD 402)
Inhalative	LC50/4 h	1.4 mg/l (rat)

· **Primary irritant effect:**

· **Skin corrosion/irritation**

Causes skin irritation.

· **Serious eye damage/irritation** No data available.

· **Respiratory or skin sensitisation**

May cause an allergic skin reaction.

· **Germ cell mutagenicity** Based on available data, the classification criteria are not met.

· **Carcinogenicity**

May cause cancer.

· **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.

· **Additional toxicological information:**

· **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**

Carc. 1B

· **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	37 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)

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

EC50/48h	8.48 mg/l (daphnia) (OECD 202)
LC50/96h	>56.12 mg/l (fish) (OECD 203)
ErC50 / 72 h	23.69 mg/l (algae) (OECD 201)

· **12.2 Persistence and degradability**

80-62-6 methyl methacrylate

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

· **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 product to reach ground water, water bodies or sewage system, even in small quantities.

Danger to drinking water if even extremely small quantities leak into soil.

SECTION 13: Disposal considerations

· **13.1 Waste treatment methods**

· **Recommendation**

Disposal must be made according to official regulations.

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

· **Uncleaned packagings:**

· **Recommendation:**

Disposal must be made according to official regulations.

Non contaminated packagings can be used for recycling.

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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

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· Transport category	2
· Tunnel restriction code	D/E
<hr/>	
· 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

· **LIST OF SUBSTANCES SUBJECT TO AUTHORISATION (UK ANNEX XIV)**

· **Information about limitation of use:**

Employment restrictions concerning young persons must be observed.

Employment restrictions concerning pregnant and lactating women must be observed.

· **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.

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H330 Fatal if inhaled.

H335 May cause respiratory irritation.

H350 May cause cancer.

H361 Suspected of damaging fertility or the unborn child.

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

H412 Harmful 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

ATE: Acute toxicity estimate values

Flam. Liq. 2: Flammable liquids – Category 2

Acute Tox. 3: Acute toxicity – Category 3

Acute Tox. 2: Acute toxicity – Category 2

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

Carc. 1B: Carcinogenicity – Category 1B

Repr. 2: Reproductive toxicity – Category 2

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

· **Sources**

(EC) 1272/2008: classification, labelling and packaging of substances and mixtures

(EC) 1907/2006: UK REACH

ADR/RID/ADN - IMDG - IATA: transport of dangerous goods by road, rail, inland waterway, with maritime vessels and for the air transport

· *** Data compared to the previous version altered.**