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

Printing date 08.10.2020 Version number 4 Revision: 08.10.2020

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. Lig. 2 H225 Highly flammable liquid and vapour.

Acute Tox. 4 H332 Harmful if inhaled.

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

N,N-dimethyl-p-toluidine

· Hazard statements

H225 Highly flammable liquid and vapour.

H332 Harmful if inhaled.

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

P304+P312 IF INHALED: Call a doctor if you feel unwell.

· 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 Chemical characterisation: Mixtures

· Description: -

· 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: 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	<i>≥</i> 2.5-<5%

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.

- · 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.

- · Information for doctor Product based on methacrylates
- 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:

Wear self-contained breathing apparatus.

Put on breathing apparatus.

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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).

Dispose of contaminated material as waste according to item 13.

· 6.4 Reference to other sections

No dangerous materials are released.

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment.

See Section 13 for information on disposal.

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

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 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

WEL Short-term value: 416 mg/m³, 100 ppm Long-term value: 208 mg/m³, 50 ppm

· DNELs

80-62-6 methyl methacrylate

worker industr., l.te., syst. 74.3 mg/Kg/d (human) Inhalative | worker industr., I.te., syst. | 210 mg/m3 (human)

· PNECs

80-62-6 methyl methacrylate

freshwater 0.94 mg/l (agua)

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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

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 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 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

· Appearance:

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

· pH-value: Not determined.

Change in condition

· Melting point/freezing point: -48 °C · Initial boiling point and boiling range: 100 °C

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· 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: · Upper:	2.1 Vol % 12.5 Vol %
· Steam pressure at 20 °C:	47 hPa
Density at 20 °C Relative density Vapour density Evaporation rate	0.94 g/cm³ Not determined. Not determined. Not determined.
Solubility in / Miscibility with Water:	Not miscible or difficult to mix
Partition coefficient: n-octanol/wate °C:	e r at 20 1.38 log POW
Viscosity: dynamic: kinematic: 9.2 Other information	Not determined. Not determined. 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 according to specifications.
- · 10.3 Possibility of hazardous reactions Exothermic polymerisation
- · 10.4 Conditions to avoid Heat, flames and sparks.
- · 10.5 Incompatible materials:

Reacts with reducing agents

Reacts with heavy metals

Reacts with peroxides and other radical forming substances

- · 10.6 Hazardous decomposition products: None
 - · Additional information: -

SECTION 11: Toxicological information

- · 11.1 Information on toxicological effects
 - Acute toxicity

Harmful if inhaled.

80-62-6 methyl methacrylate

Oral LD50 ~7,900 mg/kg (rat)

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Dermal	LD50	>5,000 mg/kg (rab) (OECD 402)
Inhalative	LC50/4 h	29.8 mg/l (rat)
99-97-8 N	,N-dimeth	yl-p-toluidine
Oral	LD50	139 mg/kg (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.

- · 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.
- · 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

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80-62-6 methyl methacrylate

EC50/48h 69 mg/l (daphnia)

LC50/96h | 191 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

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.

· European waste catalogue

18 01 06* chemicals consisting of or containing hazardous substances

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

14.1 UN-Number	
· ADR, IMDG, IATA	UN1247
14.2 UN proper shipping name	
ADR	1247 METHYL METHACRYLA
· IMDG	MONOMER, STABILIZED, solution METHYL METHACRYLATE MONOME
INDG	STABILIZED solution
·IATA	Methyl methacrylate monomer, stabiliz
	solution
14.3 Transport hazard class(es)	
· ADR	
3	
· Class	2 (E1) Flommoble liquide
· Label	3 (F1) Flammable liquids. 3
· IMDG, IATA	
A	
Class	3 Flammable liquids.
· Label	3
14.4 Packing group · ADR, IMDG, IATA	II
· · ·	11
14.5 Environmental hazards: Marine pollutant:	No
14.6 Special precautions for user	Warning: Flammable liquids.
· Kemler Number:	339
EMS Number:	F-E, <u>S-D</u>
· Stowage Category · Stowage Code	B SIM/2 Cloor of living guarters
<u> </u>	SW2 Clear of living quarters.
14.7 Transport in bulk according to Ann Marpol and the IBC Code	ex II of Not applicable.
· Transport/Additional information:	-
· ADR	
Limited quantities (LQ)	1L
Excepted quantities (EQ)	Code: E2
1 1 1 1 1 1 1 1 1 1	Maximum net quantity per inner



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packaging: 30 ml

Maximum net quantity per outer

packaging: 500 ml

· Transport category · Tunnel restriction code D/E

· Limited quantities (LQ)

Excepted quantities (ÉQ) Code: E2

Maximum net quantity per inner

packaging: 30 ml

Maximum net quantity per outer

packaging: 500 ml

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

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

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 the reproductive system through prolonged or repeated exposure. Route of exposure: Oral.

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

IMAC: 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

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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
Acute Tox. 4: Acute toxicity - inhalation – Category 4
Skin Irrit. 2: Skin corrosion/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 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3
* * Data compared to the previous version altered.