



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: **PalaVeneer Dentine 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

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

· **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.

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

P303+P361+P353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

(Contd. on page 2)

GB



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

Trade name: PalaVeneer Dentine liquid

(Contd. of page 1)

P305+P351+P338 *IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.*
P310 *Immediately call a POISON CENTER/doctor.*
P405 *Store locked up.*

- **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:** -

· **Dangerous components:**

CAS: 80-62-6 EINECS: 201-297-1 Reg.nr.: 01-2119452498-28-0000	<i>methyl methacrylate</i> <i>Flam. Liq. 2, H225; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335</i>	75-90%
CAS: 72869-86-4 EINECS: 276-957-5	<i>diurethandimethacrylate</i> <i>Aquatic Chronic 3, H412</i>	10-25%
CAS: 2082-81-7 EINECS: 218-218-1 Reg.nr.: 02-2119849716-25	<i>tetramethylene dimethacrylate</i> <i>Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335</i>	0-5%

- **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** Instantly remove any clothing soiled by the product.
 - **After inhalation** Supply fresh air; consult doctor in case of symptoms.
 - **After skin contact**
Wash with polyethylene glycol 400 and then rinse with copious amounts of water.
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.
- **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.

(Contd. on page 3)



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

Trade name: PalaVeneer Dentine liquid

(Contd. of page 2)

- **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.
Wear full protective suit.
 - **Additional information -**

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Keep away from ignition sources
Ensure adequate ventilation
Do not breathe vapor / mist / gas.
Wear protective equipment. Keep unprotected persons away.
- **6.2 Environmental precautions:** Do not allow to enter drainage system, surface or ground water.
- **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.
- **6.4 Reference to other sections**
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.
Do not breathe vapor / mist / gas.
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.
Fumes can combine with air to form an explosive mixture.
- **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:** Store away from oxidising agents.
 - **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.

GB

(Contd. on page 4)



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

Trade name: PalaVeneer Dentine liquid

(Contd. of page 3)

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	Short-term value: 416 mg/m ³ , 100 ppm
	Long-term value: 208 mg/m ³ , 50 ppm

· DNELs

80-62-6 methyl methacrylate

Dermal	worker industr., l.te., syst.	74.3 mg/Kg/d (human)
Inhalative	worker industr., l.te., syst.	210 mg/m ³ (human)

· PNECs

80-62-6 methyl methacrylate

freshwater	0.94 mg/l (aqua)
------------	------------------

· 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

For the mixture of chemicals mentioned below the penetration time has to be at least 30 minutes (Permeation according to EN 374 Part 3: Level 2).

The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

(Contd. on page 5)



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

Trade name: PalaVeneer Dentine liquid

(Contd. of page 4)

- **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:** 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/Melting range:** -48 °C
- **Boiling point/Boiling range:** 100 °C

· **Flash point:** 10 °C

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

· **Ignition temperature:** 421 °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:** 2.1 Vol %
- **Upper:** 12.5 Vol %

· **Steam pressure:** 3.6 hPa

· **Density at 20 °C** 0.949 g/cm³

- **Relative density** Not determined.
- **Vapour density at 20 °C** 3.5 g/cm³
- **Evaporation rate** Not determined.

· **Solubility in / Miscibility with**

- **Water at 20 °C:** 1.6 g/l

· **Partition coefficient (n-octanol/water):** 1.38 log POW

· **Viscosity:**

- **dynamic:** Not determined.
- **kinematic:** Not determined.

(Contd. on page 6)



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

Trade name: PalaVeneer Dentine liquid

(Contd. of page 5)

· **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**
Reacts with peroxides and other radical forming substances
Exothermic polymerisation
- **10.4 Conditions to avoid** Heat, flames and sparks.
- **10.5 Incompatible materials:** 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** 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	>5000 mg/kg (rat)
Dermal	LD50	>5000 mg/kg (rab)
Inhalative	LC50/4 h	29.8 mg/l (rat)

72869-86-4 diurethandimethacrylate

Oral	LD50	>5000 mg/kg (rat)
------	------	-------------------

2082-81-7 tetramethylene dimethacrylate

Oral	LD50	10120 mg/kg (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 (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.

GB

(Contd. on page 7)



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

Trade name: PalaVeneer Dentine liquid

(Contd. of page 6)

SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**

72869-86-4 diurethandimethacrylate

LC50/96h 10.1 mg/l (fish)

· **12.2 Persistence and degradability** Not easily biodegradable

· **12.3 Bioaccumulative potential**

Due to the distribution coefficient *n*-octanol/water an accumulation in organisms is not expected.

· **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, even in small quantities.

Danger to drinking water if even extremely 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.

· **Uncleaned packagings:**

· **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

· **14.1 UN-Number**

· **ADR, IMDG, IATA**

UN1247

· **14.2 UN proper shipping name**

· **ADR**

1247 METHYL METHACRYLATE MONOMER,
STABILIZED, mixture

· **IMDG, IATA**

METHYL METHACRYLATE MONOMER,
STABILIZED, mixture

(Contd. on page 8)



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

Trade name: PalaVeneer Dentine liquid

(Contd. of page 7)

· 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:
· 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:

-

· 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

(Contd. on page 9)



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

Trade name: PalaVeneer Dentine liquid

(Contd. of page 8)

· **UN "Model Regulation":**

UN1247, METHYL METHACRYLATE
MONOMER, STABILIZED, mixture, 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.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.
- 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
- vPvB: very Persistent and very Bioaccumulative
- Flam. Liq. 2: Flammable liquids – Category 2
- 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
- Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

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