

safety data sheet

to product

Paladon 65 Liquid

1. Identification of the substance / preparation and company

Emergency number:

Tox Info Suisse, Freiestrasse 16, 8032 Zürich; Tox-Info Suisse: 145 (24h-operation); info@toxinfo.ch; **In case of emergency: Tel. 145**; (abroad: +41 44 251 51 51); information: +41 44 251 66 66

Company name:

| • • | | |
|---------------------------------------|--------------------------------|---|
| abcdental ^o | abc dental ag | Gaswerkstrasse 6, 8952 Schlieren Tel. 044 755 51 00, Fax 044 755 51 01 |
| C NDOR A MHENRY SCHEIN" COMPANY | Condor Dental Research CO Sàrl | Ch. des Cibleries 2, CP 300, 1896 Vouvry Tel. 024 482 61 61, Fax 024 482 61 69 |
| curaden dentaldepot | Curaden AG Dentaldepot | Riedstrasse 12, 8953 Dietikon Tel. 041 319 45 00, Fax 041 319 45 90 |
| dema dent | dema dent AG | Furtbachstrasse 16, 8107 Buchs Tel. 044 838 65 65, Fax 044 838 65 66 |
| Flexdental | Flexdental Services SA | Route de la Corniche 1, 1066 Epalinges Tel. 0848 336 825, Fax 021 907 67 02 |
| JOR DI Röntgentechnik | Jordi Röntgentechnik AG | Dammstrasse 70, 4142 Münchenstein Tel. 061 417 93 93, Fax 061 417 93 94 |
| KALADENT | Kaladent AG | Schachenstrasse 2, 9016 St. Gallen Tel. 071 282 80 80, Fax 071 282 80 81 |
| LOMETRAL Die Zahnarztausstatter. | Lometral AG | Binzenholzstrasse 20, 5704 Egliswil Tel. 062 775 05 05, Fax 062 775 33 07 |
| //O/A DENT | Novadent AG | Sägereistrasse 17, 8152 Glattbrugg Tel. 044 880 20 20, Fax 044 811 04 40 |
| Smart Dentist Ich kann auch sol | Smart Dentist AG | Verenastrasse 4b, 8832 Wollerau Tel. 044 726 20 20, Fax 044 726 20 25 |



Page 1/10

Revision: 02.08.2022

Tel.: +49 (0)800 4372522

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

Printing date 02.08.2022

Version number 4 (replaces version 3)

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)

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

1,4-butandioldimethacrylate

· 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 smokina.

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

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

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

2.3 Other hazards

· Results of PBT and vPvB assessment

· PBT: Not applicable.

(Contd. on page 2)



Page 2/10

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

Printing date 02.08.2022 Version number 4 (replaces version 3) Revision: 02.08.2022

Trade name: Paladon 65 liquid

· vPvB: Not applicable.

(Contd. of page 1)

SECTION 3: Composition/information on ingredients

- · 3.2 Mixtures
 - Description: Product based on methacrylates

| · Dangerous com | ponents: | |
|-------------------|--|----------------|
| CAS: 80-62-6 | methyl methacrylate | >90% |
| EINECS: 201-297-1 | Flam. Liq. 2, H225 Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335 | |
| CAS: 2082-81-7 | 1,4-butandioldimethacrylate | <i>≥1-≤</i> 5% |
| EINECS: 218-218-1 | Skin Sens. 1B, H317 | |
| CAS: 99-85-4 | p-Mentha-1,4-diene | <0.25% |
| EINECS: 202-794-6 | Flam. Liq. 3, H226 | |
| | Repr. 2, H361 | |
| | Aquatic Chronic 2, H411 | |

[·] 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.
 - Additional information -

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

(Contd. on page 3)



Page 3/10

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

Printing date 02.08.2022

Version number 4 (replaces version 3)

Revision: 02.08.2022

Trade name: Paladon 65 liquid

(Contd. of page 2)

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 methacry | | | |
| WEL (Great Britain) | Short-term value: 416 mg/m³, 100 ppm Long-term value: 208 mg/m³, 50 ppm | | |
| IOELV (European Union) | Short-term value: 100 ppm Long-term value: 50 ppm | | |
| · DNELs | | | |
| 80-62-6 methyl methacry | /late | | |

| | 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/m3 (not defined) | | |
| | worker industrial, long term, systemic | 348.4 mg/m3 (not defined) | | |
| | worker industrial, long term, local | 208 mg/m3 (not defined) | | |
| | general population, acute, local | 208 mg/m3 (not defined) | | |
| | general population, long term, systemic | 74.3 mg/m3 (not defined) | | |
| 2082-81-7 | 1,4-butandioldimethacrylate | | | |
| Oral | general population, long term, systemic | 2.5 mg/Kg (not defined) | | |
| Dermal | worker industrial, long term, systemic | 4.2 mg/Kg/d (not defined) | | |
| | general population, long term, systemic | 2.5 mg/Kg/d (not defined) | | |
| Inhalative | worker professional, long term, systemic | 14.5 mg/m3 (not defined) | | |
| | general population, long term, systemic | 4.3 mg/m3 (not defined) | | |
| | | (Contd. on page 4 | | |

(Contd. on page 4)



Page 4/10

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

Printing date 02.08.2022 Version number 4 (replaces version 3) Revision: 02.08.2022

Trade name: Paladon 65 liquid

| | (Contd. of page 3) |
|------------------------------------|---------------------------|
| 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) |
| 2082-81-7 1,4-butandioldimethaci | rylate |
| freshwater | 0.043 mg/l (not defined) |
| marine water | 0.004 mg/l (not defined) |
| sewage treatment plant | 2 mg/l (not defined) |
| sediment, dry weight, freshwater | 3.12 mg/Kg (not defined) |
| sediment, dry weight, marine water | 0.312 mg/Kg (not defined) |
| soil, dry weight | 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 item 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 neccessary 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.

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

· Eye/face protection Tightly sealed safety glasses.

(Contd. on page 5)



Page 5/10

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

Printing date 02.08.2022 Version number 4 (replaces version 3) Revision: 02.08.2022

Trade name: Paladon 65 liquid

· Body protection: Light weight protective clothing

(Contd. of page 4)

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

General Information

· Physical state Fluid · Colour: Colourless · Smell: Ester-like

Odour threshold: Not determined.

-48 °C

· Melting point/freezing point: · Boiling point or initial boiling point and

101 °C boiling range · Flammability Not applicable.

· Lower and upper explosion limit

2.1 Vol % Lower: 12.5 Vol % · Upper:

· Flash point: 10 °C (80-62-6 methyl methacrylate)

Ignition temperature: 430 °C

Not determined. Decomposition temperature:

Paladon 65 liquid > 60 °C

SADT

· pH Mixture is non-soluble (in water). Viscosity:

Kinematic viscosity

· dynamic at 20 °C: 1 mPas

Solubility Water:

Partition coefficient n-octanol/water (log

Not determined. value)

Steam pressure at 20 °C: 47 hPa

Density and/or relative density

· Density at 20 °C 0.940 g/cm3 Relative density Not determined. · Vapour density Not determined.

· 9.2 Other information No further relevant information available.

Appearance:

Fluid Form:

· Important information on protection of health and environment, and on safety.

Product is not selfigniting. · Self-inflammability:

Explosive properties: Product is not explosive. However, formation of

explosive air/vapour mixtures is possible.

Not miscible or difficult to mix

Not determined.

Change in condition

Evaporation rate Not determined.

· Information with regard to physical hazard

classes

· Explosives Void Flammable gases Void Void · Aerosols · Oxidising gases Void

(Contd. on page 6)



Page 6/10

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

Printing date 02.08.2022 Version number 4 (replaces version 3) Revision: 02.08.2022

Trade name: Paladon 65 liquid

(Contd. of page 5)

| Void |
|-------------------------------------|
| Highly flammable liquid and vapour. |
| Void |
| |
| 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.
- 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/ | · LD/LC50 values that are relevant for classification: | | |
|------------|--|--------------------------------------|--|
| 80-62-6 m | 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 | 2082-81-7 1,4-butandioldimethacrylate | | |
| Oral | LD50 | 10,066 mg/kg (rat) (OECD 401) | |
| 99-85-4 p | 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) | |

- · 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.

(Contd. on page 7)



Page 7/10

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

Printing date 02.08.2022

Version number 4 (replaces version 3)

. .

Trade name: Paladon 65 liquid

(Contd. of page 6)

Revision: 02.08.2022

- · 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

| | atic | | |
|--|------|--|--|
| | | | |
| | | | |
| | | | |

90 62 6 mothyl motha

| 80-62-6 met | hyi methacryi | ate |
|-------------|---------------|-----|
| | | |

EC50/21d 49 mg/L (daphnia) (OECD 211)

EC50/48h 69 mg/l (daphnia) (EPA OTS 797.1300)

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 1,4-butandioldimethacrylate

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)

2082-81-7 1,4-butandioldimethacrylate

Biodegradation 84 % /28d (not defined) (OECD 310)

99-85-4 p-Mentha-1,4-diene

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

- · 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.

(Contd. on page 8)



Page 8/10

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

Printing date 02.08.2022

Version number 4 (replaces version 3)

Revision: 02.08.2022

Trade name: Paladon 65 liquid

(Contd. of page 7)

· 12.6 Endocrine disrupting properties

For information on endocrine disrupting properties see section 11.

- · 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.

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.

| 14.1 UN number or ID number ADR, IMDG, IATA | UN1247 |
|---|--|
| 14.2 UN proper shipping name ADR | 1247 METHYL METHACRYLATE MONOME STABILIZED solution |
| · IMDG, IATA | METHYL METHACRYLATE MONOME STABILIZED solution |
| 14.3 Transport hazard class(es) | |
| ADR | |
| | |
| Class | 3 (F1) Flammable liquids. |
| Label | 3 |
| · IMDG, IATA | |
| | |
| · Class | 3 Flammable liquids. |
| · Label | 3 |



Page 9/10

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

Printing date 02.08.2022 Version number 4 (replaces version 3) Revision: 02.08.2022

Trade name: Paladon 65 liquid

(Contd. of page 8) · 14.5 Environmental hazards: Marine pollutant: No · 14.6 Special precautions for user Warning: Flammable liquids. · Kemler Number: 339 EMS Number: F-E,S-D · Stowage Category · Stowage Code SW2 Clear of living quarters. · 14.7 Maritime transport in bulk according to **IMO** instruments Not applicable. Transport/Additional information: · Limited quantities (LQ) Excepted quantities (ÉQ) Code: E2 Maximum net quantity per inner packaging: Maximum net quantity per outer packaging: 500 ml · Transport category 2 · Tunnel restriction code D/E ·IMDG · Limited quantities (LQ) 1L Excepted quantities (ÉQ) Code: E2 Maximum net quantity per inner packaging: Maximum net quantity per outer packaging: 500 ml UN 1247 METHYL METHACRYLATE UN "Model Regulation":

SECTION 15: Regulatory information

· 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

MONOMER, STABILIZED SOLUTION, 3, II

- 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
- 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 İrritation.

H317 May cause an allergic skin reaction.

H335 May cause respiratory irritation.

H361 Suspected of damaging fertility or the unborn child.

(Contd. on page 10)



Page 10/10

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

Printing date 02.08.2022

Version number 4 (replaces version 3)

Revision: 02.08.2022

Trade name: Paladon 65 liquid

(Contd. of page 9)

H411 Toxic to aquatic life with long lasting effects. Abbreviations and acronyms:

SADT: Self Accelerating Decomposition Temperature SAPT: Self Accelerating Polymerisation Temperature

SAPT: Self Accelerating Polymerisation 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)

PNEC: Predicted No-Effect Concentration (ÚK REACH)

PNEC: Predicted No-Effect Concentration (UK KI 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.