

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

Printing date 15.12.2021

Version number 5

Revision: 15.12.2021

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

- **1.1 Product identifier**
  - Trade name: **Technovit 2500 Auffüllmasse**
- **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 *Ceramic repair material*
- **1.3 Details of the supplier of the safety data sheet**
  - **Manufacturer/Supplier:**  
Kulzer GmbH  
Leipziger Straße 2, 63450 Hanau (Germany)  
Tel.: +49 (0)6181 9689-2570 (Wehrheim)
  - **Informing department:** email: [technik.wehrheim@kulzer-dental.com](mailto:technik.wehrheim@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  
*Skin Sens. 1 H317 May cause an allergic skin reaction.*
- **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



GHS07

- **Signal word** *Warning*
- **Hazard-determining components of labelling:**  
*triethylen glycol dimethacrylate*
- **Hazard statements**  
*H317 May cause an allergic skin reaction.*
- **Precautionary statements**
  - P261 Avoid breathing dust/fume/gas/mist/vapours/spray.*
  - P280 Wear protective gloves.*
  - P302+P352 IF ON SKIN: Wash with plenty of soap and water.*
  - 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.
    - **vPvB:** Not applicable.

**SECTION 3: Composition/information on ingredients**

- **3.2 Chemical characterisation: Mixtures**

· **Dangerous components:**

CAS: 109-16-0	triethylen glycol dimethacrylate	≥5-≤10%
EINECS: 203-652-6	Skin Sens. 1B, H317	
Reg.nr.: 01-2119969287-21-xxxx		

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**Trade name: Technovit 2500 Auffüllmasse**

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CAS: 79-41-4 EINECS: 201-204-4	methacrylic acid Acute Tox. 3, H311 Skin Corr. 1A, H314; Eye Dam. 1, H318 Acute Tox. 4, H302; Acute Tox. 4, H332; STOT SE 3, H335 Specific concentration limit: STOT SE 3; H335: C ≥ 1 %	<1%
CAS: 131-57-7 EINECS: 205-031-5	Oxybenzone Aquatic Acute 1, H400; 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**
  - **General information**  
Personal protection for the First Aider.  
Instantly remove any clothing soiled by the product.
  - **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. If symptoms persist, consult doctor.  
Remove contact lenses, if present and easy to do. Continue rinsing.
  - **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** Allergic reactions
- **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** CO<sub>2</sub>, sand, extinguishing powder. Do not use water.
  - **For safety reasons unsuitable extinguishing agents** Water.
- **5.2 Special hazards arising from the substance or mixture**  
Formation of toxic gases is possible during heating or in case of fire.  
Can be released in case of fire  
Carbon dioxide (CO<sub>2</sub>)  
Carbon monoxide (CO)
- **5.3 Advice for firefighters**
  - **Protective equipment:**  
Wear self-contained breathing apparatus.  
(EN 133)
  - **Additional information**  
Cool endangered containers with water spray jet.  
Collect contaminated fire fighting water separately. It must not enter drains.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Avoid contact with eyes and skin.  
Ensure adequate ventilation

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Wear protective equipment. Keep unprotected persons away.

· **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.

· **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**

No special measures required.

Avoid contact with eyes and skin.

Ensure good ventilation/exhaustion at the workplace.

Keep away from heat and direct sunlight.

· **Handling**

do not mix with

reducing agent

amine

organic peroxides

Radical initiator

Strong acids

metals

· **Information about protection against explosions and fires:**

Protect from heat.

Keep ignition sources away - Do not smoke.

· **7.2 Conditions for safe storage, including any incompatibilities**

· **Storage**

· **Requirements to be met by storerooms and containers:**

Protect from the effects of light.

Store in cool location.

· **Information about storage in one common storage facility:** Store away from foodstuffs.

· **Further information about storage conditions:**

Protect from humidity and keep away from water.

Protect from heat and direct sunlight.

Store in a cool place.

· **7.3 Specific end use(s)** No further relevant information available.

## SECTION 8: Exposure controls/personal protection

· **8.1 Control parameters**

· **Additional information about design of technical systems:** No further data; see item 7.

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

**79-41-4 methacrylic acid**

WEL (Great Britain)	Short-term value: 143 mg/m <sup>3</sup> , 40 ppm Long-term value: 72 mg/m <sup>3</sup> , 20 ppm
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**· DNELs**
**109-16-0 triethylen glycol dimethacrylate**

Oral	general population, long term, systemic	8.33 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	13.9 mg/Kg/d (not defined)
	general population, long term, systemic	8.33 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, systemic	48.5 mg/m <sup>3</sup> (not defined)
	general population, long term, systemic	14.5 mg/m <sup>3</sup> (not defined)

**79-41-4 methacrylic acid**

Dermal	worker industrial, long term, systemic	4.25 mg/Kg/d (not defined)
	general population, long term, systemic	2.55 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, local	88 mg/m <sup>3</sup> (not defined)
	worker professional, long term, systemic	29.6 mg/m <sup>3</sup> (not defined)
	general population, long term, systemic	6.3 mg/m <sup>3</sup> (not defined)
	general population, long term, local	6.55 mg/m <sup>3</sup> (not defined)

**131-57-7 Oxybenzone**

Oral	general population, long term, systemic	2 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	39 mg/Kg/d (not defined)
	general population, long term, systemic	20 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, systemic	27.7 mg/m <sup>3</sup> (not defined)
	general population, long term, systemic	6.8 mg/m <sup>3</sup> (not defined)

**· PNECs**
**109-16-0 triethylen glycol dimethacrylate**

freshwater	0.016 mg/l (not defined)
marine water	0.002 mg/l (not defined)
sewage treatment plant	1.7 mg/l (not defined)
sediment, dry weight, freshwater	0.185 mg/Kg (not defined)
sediment, dry weight, marine water	0.018 mg/Kg (not defined)
soil, dry weight	0.027 mg/Kg (not defined)

**131-57-7 Oxybenzone**

freshwater	0.00067 mg/l (not defined)
marine water	0.000067 mg/l (not defined)
sewage treatment plant	10 mg/l (not defined)
sediment, dry weight, freshwater	0.066 mg/Kg (not defined)
sediment, dry weight, marine water	0.007 mg/Kg (not defined)
soil, dry weight	0.013 mg/Kg (not defined)

· **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**

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

Do not eat or drink while working.

Avoid contact with the eyes and skin.

Instantly remove any soiled and impregnated garments.

Wash hands during breaks and at the end of the work.

**· Breathing equipment:**

Use breathing protection in case of insufficient ventilation.

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Filter A/P2.

**· Protection of hands:**

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

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

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.

NBR: acrylonitrile-butadiene rubber (0,11 mm)

**· 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.

>30 min

· **Eye protection:** eye protection (EN 166)

· **Body protection:** Light weight protective clothing

**· Limitation and supervision of exposure into the environment**

Do not allow to enter the ground/soil.

Do not allow to enter drainage system, surface or ground water.

**SECTION 9: Physical and chemical properties**

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

**· General Information**

**· Appearance:**

· **Form:**

Pasty

· **Colour:**

Colourless

· **Smell:**

Odourless

· **Odour threshold:**

Not determined.

· **pH-value:**

Not determined.

**· Change in condition**

· **Melting point/freezing point:**

Not determined

· **Initial boiling point and boiling range:** Not determined

· **Flash point:**

Not applicable

· **Inflammability (solid, gaseous)**

Not applicable.

· **Decomposition temperature:**

Not determined.

· **Self-inflammability:**

Product is not selfigniting.

· **Explosive properties:**

Product is not explosive.

**· Critical values for explosion:**

· **Lower:**

Not determined.

· **Upper:**

Not determined.

· **Steam pressure:**

Not determined.

· **Density**

Not determined

· **Relative density**

Not determined.

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· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with	
· Water:	Not miscible or difficult to mix
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
· dynamic:	Not determined.
· kinematic:	Not determined.
· Solvent content:	
· VOC EU	g/l
· 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 Danger of polymerisation
- 10.4 Conditions to avoid Heat, flames and sparks.
- 10.5 Incompatible materials:
  - amine
  - organic peroxides
  - Radical initiator
  - reducing agent
  - Strong acids
  - metals
- 10.6 Hazardous decomposition products: None

**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:

**109-16-0 triethylen glycol dimethacrylate**

Oral	LD50	8,300 mg/kg (rat)
Dermal	LD50	>2,000 mg/kg (mouse)

**79-41-4 methacrylic acid**

Oral	LD50	1,320 mg/kg (rat) (OECD 401)
Dermal	LD50	500-1,000 mg/kg (rabbit)
Inhalative	LC50/4 h	7.1 mg/l (rat) (OECD 403)

**131-57-7 Oxybenzone**

Oral	LD50	>12,800 mg/kg (rat) (OECD 401)
Dermal	LD50	>16,000 mg/kg (rabbit) (OECD 402)

· Primary irritant effect:

- Skin corrosion/irritation Based on available data, the classification criteria are not met.
- Serious eye damage/irritation  
Based on available data, the classification criteria are not met.

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- **Respiratory or skin sensitisation**  
May cause an allergic skin reaction.
- **Additional toxicological information:**
  - **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** Based on available data, the classification criteria are not met.
  - **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**

· **Aquatic toxicity:**

**109-16-0 triethylen glycol dimethacrylate**

EC50/21d	51.9 mg/L (daphnia) (OECD 211)
LC50/96h	16.4 mg/l (fish) (OECD 203)
NOEC / 21d	32 mg/l (daphnia) (OECD 211)
ErC50 / 72 h	>100 mg/l (algae) (OECD 201)
NOEC / 72h	18.6 mg/l (algae) (OECD 201)
EbC50 / 72h	72.8 mg/l (algae) (OECD 201)

**79-41-4 methacrylic acid**

EC50/48h	>130 mg/l (daphnia) (EPA OTS 797.1300)
LC50/96h	85 mg/l (fish) (EPA OTS 797.1400)
NOEC / 21d	53 mg/l (daphnia)
ErC50 / 72 h	45 mg/l (algae) (OECD 201)
NOEC / 72h	8.2 mg/l (algae) (OECD 201)
NOEC / 96h	12 mg/l (fish) (EPA OTS 797.1400)
NOEC / 48h	130 mg/l (daphnia) (EPA OTS 797.1300)

**131-57-7 Oxybenzone**

EC50/48h	1.87 mg/l (daphnia) (OECD 202)
LC50/96h	3.8 mg/l (fish) (OECD 203)
ErC50 / 72 h	0.67 mg/l (algae) (OECD 201)
NOEC / 72h	0.18 mg/l (algae) (OECD 201)
NOEC / 96h	0.72 mg/l (fish) (OECD 203)
NOEC / 48h	1.15 mg/l (daphnia) (OECD 202)

· **12.2 Persistence and degradability**

**109-16-0 triethylen glycol dimethacrylate**

Biodegradation 85 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)

**79-41-4 methacrylic acid**

Biodegradation 86 % /28d (not defined) (OECD 301D)

**131-57-7 Oxybenzone**

Biodegradation 60-70 % /28d (not defined)

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· **12.3 Bioaccumulative potential**

**131-57-7 Oxybenzone**

Bloconcentration factor (BCF) >33-<160 (fish) (OECD 305)

· **12.4 Mobility in soil** No further relevant information available.

· **Additional ecological information:**

· **General notes:**

Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.

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** Smaller quantities can be disposed with household garbage.

· **Uncleaned packagings:**

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

**SECTION 14: Transport information**

· **14.1 UN-Number**

· **ADR, ADN, IMDG, IATA**

Void

· **14.2 UN proper shipping name**

· **ADR, ADN, IMDG, IATA**

Void

· **14.3 Transport hazard class(es)**

· **ADR, ADN, IMDG, IATA**

· **Class**

Void

· **14.4 Packing group**

· **ADR, IMDG, IATA**

Void

· **14.5 Environmental hazards:**

· **Marine pollutant:**

No

· **14.6 Special precautions for user**

Not applicable.

· **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**

Not applicable.

· **Transport/Additional information:**

-

· **UN "Model Regulation":**

Void

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### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
  - **Directive 2012/18/EU**
    - **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**
  - H302 Harmful if swallowed.
  - H311 Toxic in contact with skin.
  - H314 Causes severe skin burns and eye damage.
  - H317 May cause an allergic skin reaction.
  - H318 Causes serious eye damage.
  - H332 Harmful if inhaled.
  - H335 May cause respiratory irritation.
  - H400 Very toxic to aquatic life.
  - H411 Toxic to aquatic life with long lasting effects.
- **Abbreviations and acronyms:**
  - 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)
  - VOCV: Lenkungsabgabe auf flüchtigen organischen Verbindungen, Schweiz (Swiss Ordinance on volatile organic compounds)
  - 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
  - Acute Tox. 4: Acute toxicity – Category 4
  - Acute Tox. 3: Acute toxicity – Category 3
  - Skin Corr. 1A: Skin corrosion/irritation – Category 1A
  - Eye Dam. 1: Serious eye damage/eye irritation – Category 1
  - Skin Sens. 1: Skin sensitisation – Category 1
  - Skin Sens. 1B: Skin sensitisation – Category 1B
  - STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
  - Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
  - Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2
- **Sources**
  - (EC) 1272/2008: classification, labelling and packaging of substances and mixtures
  - (EC) 1907/2006: 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.**