

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

Printing date 15.06.2021


Version number 1

Revision: 15.06.2021

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

- **1.1 Product identifier**
  - Trade name: **Technovit 25xx / Technovit 25xxx  
Keramikreparaturmaterial**
- **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.  
Aquatic Chronic 3      H412 Harmful to aquatic life with long lasting effects.
  - **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  
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahehexadecane-1,16-diyl bismethacrylate
  - **Hazard statements**  
H317 May cause an allergic skin reaction.  
H412 Harmful to aquatic life with long lasting effects.
  - **Precautionary statements**  
P273      Avoid release to the environment.  
P280      Wear protective gloves/protective clothing/eye protection/face protection.  
P302+P352 IF ON SKIN: Wash with plenty of soap and water.  
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
  - **Additional information:**  
Contains isocyanates. May produce an allergic reaction.
  - **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: 109-16-0 EINECS: 203-652-6 Reg.nr.: 01-2119969287-21-xxxx	triethylen glycol dimethacrylate ----- Skin Sens. 1B, H317	≥5-≤10%
CAS: 72869-86-4 EINECS: 276-957-5 Reg.nr.: 01-2120751202-68-xxxx	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12- diazahexadecane-1,16-diyl bismethacrylate ----- Aquatic Chronic 2, H411 Skin Sens. 1B, H317	≥5-≤10%

· **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**

In case of persistent symptoms consult doctor.

Rinse out mouth and then drink plenty of water.

· **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>, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.· **For safety reasons unsuitable extinguishing agents** Water with a full water jet.

#### · 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)

Under certain fire conditions, traces of other toxic gases cannot be excluded.

#### · 5.3 Advice for firefighters

· **Protective equipment:**

Wear self-contained breathing apparatus.

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· **Additional information** Cool endangered containers with water spray jet.

### SECTION 6: Accidental release measures

· **6.1 Personal precautions, protective equipment and emergency procedures**

Avoid contact with eyes and skin.

Ensure adequate ventilation

Wear protective equipment. Keep unprotected persons away.

Keep away from ignition sources

· **6.2 Environmental precautions:**

Prevent material from reaching sewage system, holes and cellars.

Damp down gases/fumes/haze with water spray jet.

· **6.3 Methods and material for containment and cleaning up:**

Dispose of the material collected according to regulations.

Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).

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**

Prevent formation of aerosols.

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

Radical initiator

organic peroxides

Strong bases

reducing agent

Strong oxidizers

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:** Store in cool location.

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

· **Further information about storage conditions:**

Store in a cool place.

Protect from heat and direct sunlight.

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

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**SECTION 8: Exposure controls/personal protection**

· **8.1 Control parameters**

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

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

Not required.

· **DNELs**

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

Oral	ge.pop., l.te, syst.	8.33 mg/Kg (nd)
Dermal	worker industr., l.te., syst.	13.9 mg/Kg/d (nd)
	ge.pop., l.te, syst.	8.33 mg/Kg/d (nd)
Inhalative	worker industr., l.te., syst.	48.5 mg/m <sup>3</sup> (nd)
	ge.pop., l.te, syst.	14.5 mg/m <sup>3</sup> (nd)

**72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahehexadecane-1,16-diyl bismethacrylate**

Oral	ge.pop., l.te, syst.	0.3 mg/Kg (nd)
Dermal	worker industr., l.te., syst.	1.3 mg/Kg/d (nd)
	ge.pop., l.te, syst.	0.7 mg/Kg/d (nd)
Inhalative	worker industr., l.te., syst.	3.3 mg/m <sup>3</sup> (nd)
	ge.pop., l.te, syst.	0.6 mg/m <sup>3</sup> (nd)

· **PNECs**

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

freshwater	0.016 mg/l (nd)
marine water	0.002 mg/l (nd)
STP	1.7 mg/l (nd)
sedim., dw, fre.wat.	0.185 mg/Kg (nd)
sedim., dw, mar.wat.	0.018 mg/Kg (nd)
soil,dw	0.027 mg/Kg (nd)

**72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahehexadecane-1,16-diyl bismethacrylate**

freshwater	0.01 mg/l (nd)
marine water	0.001 mg/l (nd)
STP	3.61 mg/l (nd)
sedim., dw, fre.wat.	4.56 mg/Kg (nd)
sedim., dw, mar.wat.	0.46 mg/Kg (nd)
soil,dw	0.91 mg/Kg (nd)

· **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**

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

Do not eat or drink while working.

Avoid contact with the eyes and skin.

Instantly remove any soiled and impregnated garments.

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

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· **Breathing equipment:**

Use breathing protection in case of insufficient ventilation.  
Filter A/P2.

· **Protection of hands:**

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

· **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.

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

· **Penetration time of glove material**

The exact break through 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:**

Fluid

· **Colour:**

White

· **Smell:**

Characteristic

· **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.

Not determined.

· **Critical values for explosion:**

· **Lower:**

Not determined.

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· <b>Upper:</b>	Not determined.
· <b>Steam pressure:</b>	Not determined.
· <b>Density</b>	Not determined
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with</b>	
· <b>Water:</b>	Not miscible or difficult to mix
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b>	
· <b>dynamic:</b>	Not determined.
· <b>kinematic:</b>	Not determined.
· <b>9.2 Other information</b>	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** 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
  - metals
- **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:**

#### 109-16-0 triethylen glycol dimethacrylate

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

#### 72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazaheptadecane-1,16-diyl bismethacrylate

Oral	LD50	>5,000 mg/kg (rat) (OECD 401)
Dermal	LD50	>2,000 mg/kg (rat) (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)

#### **72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate**

EC50/48h	>1.2 mg/l (daphnia) (OECD 202)
LC50/96h	10.1 mg/l (fish) (OECD 203)
ErC50 / 72 h	>0.68 mg/l (algae) (OECD 201)
NOEC / 72h	0.21 mg/l (algae) (OECD 201)

### · 12.2 Persistence and degradability

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

Biodegradation 85 % /28d (nd) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)

#### **72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate**

Biodegradation 22 % /28d (nd) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)

### · 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.

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### 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.

### SECTION 14: Transport information

- |  |                 |
|--|-----------------|
| · <b>14.1 UN-Number</b><br>· ADR, IMDG, IATA                                     | Void            |
| · <b>14.2 UN proper shipping name</b><br>· ADR, IMDG, IATA                       | Void            |
| · <b>14.3 Transport hazard class(es)</b><br>· ADR, ADN, IMDG, IATA<br>· Class    | Void            |
| · <b>14.4 Packing group</b><br>· ADR, IMDG, IATA                                 | Void            |
| · <b>14.5 Environmental hazards:</b>   | Not applicable. |
| · <b>14.6 Special precautions for user</b>                                       | Not applicable. |
| · <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b> | Not applicable. |
| · <b>Transport/Additional information:</b>                                       | -               |
| · <b>UN "Model Regulation":</b>  | Void            |

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
  - **Directive 2012/18/EU**
    - **Named dangerous substances - ANNEX I** None of the ingredients is listed.
    - **Information about limitation of use:**  
Employment restrictions concerning young persons 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**  
H317 May cause an allergic skin reaction.

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*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)

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

Skin Sens. 1: Skin sensitisation – Category 1

Skin Sens. 1B: Skin sensitisation – Category 1B

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – 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: REACH

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

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