

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

Printing date 18.10.2022

Version number 5 (replaces version 4)

Revision: 18.10.2022

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

- **1.1 Product identifier**
 - Trade name: **Technovit 8100 hardener 2**
- **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** Resin for histological examinations
- **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
- **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**
The product is not classified, according to the GB CLP regulation.
- **2.2 Label elements**
 - **Labelling according to Regulation (EC) No 1272/2008** Void
 - **Hazard pictograms** Void
 - **Signal word** Void
 - **Hazard statements** Void
 - **Additional information:**
Safety data sheet available on request.
- **2.3 Other hazards**
 - **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.2 Mixtures**

- **Dangerous components:**

| | | |
|-------------------|---|------|
| CAS: 4913-13-7 | <i>N,N</i> -dimethyl-3,5-xylidine | 0-5% |
| EINECS: 225-539-0 | STOT RE 2, H373 Acute Tox. 4, H302; Acute Tox. 4, H312; Acute Tox. 4, H332; Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335 ATE: LD50 oral: 500 mg/kg LD50 dermal: 1,100 mg/kg LC50/4 h inhalative: 1.5 mg/l | |

- **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** No special measures required.
 - **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.

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- **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**
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, 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 (CO₂)
Carbon monoxide (CO)
Nitrogen oxides (NO_x)
- **5.3 Advice for firefighters**
 - **Protective equipment:**
Wear self-contained breathing apparatus.
(EN 133)
 - **Additional information**
Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
Do not breathe vapor / mist / gas.
Ensure adequate ventilation
Keep away from ignition sources
- **6.2 Environmental precautions:**
Do not allow to enter drainage system, surface or ground water.
Keep dirty washing water for appropriate disposal.
Do not allow to enter the ground/soil.
- **6.3 Methods and material for containment and cleaning up:**
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 8 for information on personal protection equipment.
See Section 7 for information on safe handling

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
Keep containers tightly sealed.
Do not breathe vapor / mist / gas.

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Ensure good ventilation/exhaustion at the workplace.

Keep away from heat and direct sunlight.

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

Fumes can combine with air to form an explosive mixture.

Use explosion-proof apparatus / fittings and spark-proof tools.

Protect against electrostatic charges.

Do not spray on flames or red-hot objects.

Keep ignition sources away - Do not smoke.

· **Handling**

do not mix with

Strong acids

Strong oxidizers

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

· **Storage**

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

Store in cool, dry place in tightly closed containers.

· **Information about storage in one common storage facility:** Not required.

· **Further information about storage conditions:** None.

· **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:**

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

Not required.

· **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**

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

Keep away from foodstuffs, beverages and food.

Do not eat or drink while working.

Do not inhale gases / fumes / aerosols.

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

· **Breathing equipment:**

Use breathing protection in case of insufficient ventilation.

Filter A/P2.

· **Hand protection**

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

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

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. 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.

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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/face protection** eye protection (EN 166)
- **Body protection:** Light weight protective clothing
- **Environmental exposure controls**
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**

- | | |
|---|---|
| · Physical state | Fluid |
| · Colour: | Colourless |
| · Smell: | Odourless |
| · Odour threshold: | Not determined. |
| · Melting point/freezing point: | Not determined |
| · Boiling point or initial boiling point and boiling range | >150 °C (25322-68-3 polyethylene glycol) |
| · Flammability | Not applicable. |
| · Lower and upper explosion limit | |
| · Lower: | Not determined. |
| · Upper: | Not determined. |
| · Flash point: | 91 °C (4913-13-7 N,N-dimethyl-3,5-xylidine) |
| · Ignition temperature: | not determined |
| | Ingredients: |
| | No information available |
| | Not determined. |

· **Decomposition temperature:**

· **SADT**

- | | |
|--|------------------------|
| · pH | Not determined. |
| · Viscosity: | |
| · Kinematic viscosity | Not determined. |
| · dynamic: | Not determined. |
| · Solubility | |
| · Water: | Partly miscible |
| · Partition coefficient n-octanol/water (log value) | Not determined. |
| · Steam pressure at 20 °C: | >0 hPa |
| · Density and/or relative density | |
| · Density at 20 °C | 1.15 g/cm ³ |
| · Relative density | Not determined. |
| · Vapour density | Not determined. |

· **9.2 Other information**

No further relevant information available.

· **Appearance:**

- | | |
|----------------|-------|
| · Form: | Fluid |
|----------------|-------|

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

- | | |
|--------------------------------|------------------------------|
| · Self-inflammability: | Product is not selfigniting. |
| · Explosive properties: | Product is not explosive. |

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| | |
|--|-----------------|
| · Solvent content: | |
| · VOC EU | g/l |
| · Change in condition | |
| · Evaporation rate | Not determined. |
| · Information with regard to physical hazard classes | |
| · Explosives | Void |
| · Flammable gases | Void |
| · Aerosols | Void |
| · Oxidising gases | Void |
| · Gases under pressure | Void |
| · Flammable liquids | Void |
| · Flammable solids | Void |
| · Self-reactive substances and mixtures | Void |
| · Pyrophoric liquids | Void |
| · Pyrophoric solids | Void |
| · Self-heating substances and mixtures | Void |
| · Substances and mixtures, which emit flammable gases in contact with water | Void |
| · Oxidising liquids | Void |
| · Oxidising solids | Void |
| · Organic peroxides | Void |
| · Corrosive to metals | Void |
| · Desensitised explosives | 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** Heat, flames and sparks.
- **10.5 Incompatible materials:**
 - Strong oxidizers
 - Strong acids
- **10.6 Hazardous decomposition products:** None

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.
 - Based on available data, the classification criteria are not met.

· **LD/LC50 values that are relevant for classification:**

4913-13-7 N,N-dimethyl-3,5-xylidine

| | | |
|--------|------|-------------------|
| Oral | LD50 | 500 mg/kg (ATE) |
| Dermal | LD50 | 1,100 mg/kg (ATE) |

- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Germ cell mutagenicity**
 - Based on available data, the classification criteria are not met.
 - Based on available data, the classification criteria are not met.

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- **Carcinogenicity**
Based on available data, the classification criteria are not met.
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.
Based on available data, the classification criteria are not met.
- **STOT-repeated exposure**
Based on available data, the classification criteria are not met.
Based on available data, the classification criteria are not met.
- **Aspiration hazard**
Based on available data, the classification criteria are not met.
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**
 - **Aquatic toxicity:** *No further relevant information available.*
- **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.*
- **12.5 Results of PBT and vPvB assessment**
 - **PBT:** *Not applicable.*
 - **vPvB:** *Not applicable.*
- **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
 - **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.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
 - **Recommendation**
Small quantities can be polymerized with the matching system component(s) and the cured solid material can be disposed of with the regular garbage.
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 or ID number**
 - **ADR, ADN, IMDG, IATA** Void

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| | |
|--|-----------------|
| · 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 Maritime transport in bulk according to IMO instruments | Not applicable. |
| · Transport/Additional information: | - |
| · UN "Model Regulation": | Void |

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.
 - H312 Harmful in contact with skin.
 - H315 Causes skin irritation.
 - H319 Causes serious eye irritation.
 - H332 Harmful if inhaled.
 - H335 May cause respiratory irritation.
 - H373 May cause damage to organs through prolonged or repeated exposure.
- **Abbreviations and acronyms:**
 - SADT: Self Accelerating Decomposition 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)
 - VOCV: Lenkungsabgabe auf flüchtigen organischen Verbindungen, Schweiz (Swiss Ordinance on volatile organic compounds)
 - LC50: Lethal concentration, 50 percent

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*LD50: Lethal dose, 50 percent**PBT: Persistent, Bioaccumulative and Toxic**vPvB: very Persistent and very Bioaccumulative**Acute Tox. 4: Acute toxicity – Category 4**Skin Irrit. 2: Skin corrosion/irritation – Category 2**Eye Irrit. 2: Serious eye damage/eye irritation – Category 2**STOT SE 3: Specific target organ toxicity (single exposure) – Category 3**STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2***Sources***(EC) 1272/2008: classification, labelling and packaging of substances and mixtures**(EC) 1907/2006: UK REACH**ADR/RID/ADN - IDMG - 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.**

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