

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

Printing date 18.10.2022

Version number 7 (replaces version 6)

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

- · 1.1 Product identifier
 - Trade name: Technovit 9100 hardener 2 new
- · 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

Acute Tox. 4 H302 Harmful if swallowed.

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation. STOT SE 3 H335 May cause respiratory irritation.

STOT RE 2 H373 May cause damage to organs through prolonged or repeated exposure.

· 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





GHS07 GHS08

- · Signal word Warning
- · Hazard-determining components of labelling:

N,N-dimethyl-3,5-xylidine

Hazard statements

H302 Harmful if swallowed.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H373 May cause damage to organs through prolonged or repeated exposure.

Precautionary statements

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

P280 Wear protective gloves/protective clothing/eye protection/face protection.
P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

· 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 Mixtures
 - Description: -

· Dangerous components:	
CAS: 4913-13-7 N,N-dimethyl-3,5-xylidine	20-<30%
EINECS: 225-539-0 STOT RE 2, H373	
Acute Tox. 4, H302; Acute Tox. 4, H312; Acute Tox. 4, H332; Skir	1
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

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

Take affected persons into the open air.

Personal protection for the First Aider.

After inhalation

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

In case of unconsciousness bring patient into stable side position for transport.

· After skin contact

Instantly wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

· 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.

Instantly call for 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

Can form explosive gas-air mixtures.

Formation of toxic gases is possible during heating or in case of fire.

Can be released in case of fire

Carbon dioxide (CO2)

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Carbon monoxide (CO) Nitrogen oxides (NOx)

5.3 Advice for firefighters

- **Protective equipment:** Wear self-contained breathing apparatus.
- 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.

Avoid contact with eyes and skin.

Do not breathe vapor / mist / gas.

Ensure adequate ventilation

Keep away from ignition sources

6.2 Environmental precautions:Do not allow to enter the ground/soil.

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).

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

Keep containers tightly sealed.

Avoid contact with eyes and skin.

Do not breathe vapor / mist / gas.

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.

Protect from heat.

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
 - - 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.

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· 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

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.

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:

Use breathing protection in case of insufficient ventilation.

Filter A/P2.

· Hand protection

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

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

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

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

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

>30 min

· Eve/face protection Safety glasses

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.

GB



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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

>150 °C (25322-68-3 polyethylene glycol) boiling range · Flammability Not applicable.

· Lower and upper explosion limit

Not determined. Lower: Upper: Not determined.

91 °C (4913-13-7 N,N-dimethyl-3,5-xylidine) · Flash point:

Not determined. · Decomposition temperature:

SADT

Not determined.

Viscosity:

· Kinematic viscosity Not determined. Not determined. · dynamic: Solubility

Water:

Not miscible or difficult to mix

Partition coefficient n-octanol/water (log

Not determined. value)

· Steam pressure at 20 °C: >0 hPa

· Density and/or relative density

Density at 20 °C 1.08791 g/cm³ 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.

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

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· 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:

10.5 incompatible materia

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 Harmful if swallowed.
 - · 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 Causes skin irritation.
- · Serious eye damage/irritation Causes serious eye irritation.
- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · 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
- May cause damage to organs through prolonged or repeated exposure.
- 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
 - · 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.

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· 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:

Avoid transfer into the environment.

Do not allow product to reach ground water, water bodies or sewage system, even in small

Danger to drinking water if even extremely 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. Larger quantities must be disposed of following the regulations of the local authorities.

- · Waste disposal key number: 55370
- · Uncleaned packagings:
 - Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport informati	on	
· 14.1 UN number or ID 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 Maritime transport in bulk accordin IMO instruments	g to 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
 - · Named dangerous substances ANNEX I None of the ingredients is listed.
 - · 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

GHS: Globally Harmonised System of Classification and Labelling of Chemical 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) 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
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

(EĆ) 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.