

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

Printing date 07.06.2021

Version number 6

Revision: 07.06.2021

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

- **1.1 Product identifier**
 - Trade name: **Technovit 9100 Hardener 1 New/ Technovit 7100 Hardener 1**
- **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**
 - Org. Perox. D H242 Heating may cause a fire.
 - Eye Irrit. 2 H319 Causes serious eye irritation.
 - Skin Sens. 1 H317 May cause an allergic skin reaction.
 - Repr. 1B H360D May damage the unborn child.
 - Aquatic Acute 1 H400 Very toxic to aquatic life.
 - Aquatic Chronic 1 H410 Very toxic 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**



GHS02 GHS07 GHS08 GHS09

· **Signal word** Danger

· **Hazard-determining components of labelling:**

dicyclohexyl phthalate
 dibenzoyl peroxide

· **Hazard statements**

H242 Heating may cause a fire.
 H319 Causes serious eye irritation.
 H317 May cause an allergic skin reaction.
 H360D May damage the unborn child.
 H410 Very toxic to aquatic life with long lasting effects.

· **Precautionary statements**

P201 Obtain special instructions before use.
 P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
 P234 Keep only in original packaging.
 P280 Wear protective gloves/protective clothing/eye protection/face protection.

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P308+P313 IF exposed or concerned: Get medical advice/attention.
P370+P378 In case of fire: Use for extinction: CO2, powder or water spray.

· **Additional information:**
 Restricted to professional users.

· **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**

· **Description:** -

· **Dangerous components:**

CAS: 84-61-7 EINECS: 201-545-9 Reg.nr.: 01-2119978223-34-xxxx	dicyclohexyl phthalate Repr. 1B, H360D Aquatic Chronic 2, H411 Skin Sens. 1, H317	≥25-≤75%
CAS: 94-36-0 EINECS: 202-327-6 Reg.nr.: 01-2119511472-50-xxxx	dibenzoyl peroxide Self-react. B, H241; Org. Perox. B, H241 Aquatic Acute 1, H400 (M=10); Aquatic Chronic 1, H410 (M=10) Eye Irrit. 2, H319; Skin Sens. 1, H317	≥25-≤75%

· **SVHC**

84-61-7 dicyclohexyl phthalate

· **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.

Take affected persons out of danger area and instruct to lie down.

· **After inhalation** *Supply fresh air; consult doctor in case of symptoms.*

· **After skin contact**

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

Instantly wash with water and soap and rinse thoroughly.

· **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**

Seek medical treatment.

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**

CO2, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.

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- **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.
Combustible solids. Fine dust clouds can form explosive mixtures with air.
Can be released in case of fire
Carbon dioxide (CO₂)
Carbon monoxide (CO)
- **5.3 Advice for firefighters**
 - **Protective equipment:**
Wear self-contained breathing apparatus.
(EN 133)
Wear full protective suit.
 - **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**
Wear protective equipment. Keep unprotected persons away.
Avoid contact with eyes and skin.
Do not breathe vapor / mist / gas.
Ensure adequate ventilation
Keep people at a distance and stay on the windward side.
Wear protective clothing.
Avoid causing dust.
- **6.2 Environmental precautions:**
Damp down gases/fumes/haze with water spray jet.
Do not allow to enter the ground/soil.
Do not allow to enter drainage system, surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Collect mechanically.
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**
Wear protective equipment. Keep unprotected persons away.
Provide suction extractors if dust is formed.
Avoid contact with eyes and skin.
Do not breathe vapor / mist / gas.
Ensure good ventilation/exhaustion at the workplace.
Any deposit of dust which cannot be avoided must be removed regularly.
Keep away from heat and direct sunlight.
Keep containers tightly sealed.
Prevent formation of dust.
- **Handling**
do not mix with
metals
reducing agent
Radical initiator

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Strong bases

Strong acids

Information about protection against explosions and fires:

Protect from heat.

Protect against electrostatic charges.

Do not spray on flames or red-hot objects.

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:

No special requirements.

Store in cool, dry place in tightly closed containers.

Information about storage in one common storage facility:

Do not store together with reducing agents, heavy-metal compounds, acids and alkalis.

Further information about storage conditions:

Store in a cool place.

Protect from heat and direct sunlight.

Recommended storage temperature: < 25°C

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:

84-61-7 dicyclohexyl phthalate

WEL (Great Britain) Long-term value: 5 mg/m³

94-36-0 dibenzoyl peroxide

WEL (Great Britain) Long-term value: 5 mg/m³

71-43-2 benzene

WEL (Great Britain) Long-term value: 3.25 mg/m³, 1 ppm
 Carc; Sk

BOELV (European Union) Long-term value: 3.25 mg/m³, 1 ppm
 Skin

124-38-9 carbon dioxide

WEL (Great Britain) Short-term value: 27400 mg/m³, 15000 ppm
 Long-term value: 9150 mg/m³, 5000 ppm

IOELV (European Union) Long-term value: 9000 mg/m³, 5000 ppm

DNELs

84-61-7 dicyclohexyl phthalate

Oral	ge.pop., l.te, syst.	0.25 mg/Kg (nd)
Dermal	worker industr., l.te., syst.	0.5 mg/Kg/d (nd)
	ge.pop., l.te, syst.	0.25 mg/Kg/d (nd)
Inhalative	worker industr., l.te., syst.	35.2 mg/m ³ (nd)
	ge.pop., l.te, syst.	0.87 mg/m ³ (nd)

94-36-0 dibenzoyl peroxide

Oral	ge.pop., l.te, syst.	2 mg/Kg (nd)
Dermal	worker industr., l.te., syst.	13.3 mg/Kg/d (nd)

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Inhalative worker industr., l.te., syst. 39 mg/m³ (nd) (Contd. of page 4)

· **PNECs**

84-61-7 dicyclohexyl phthalate

freshwater	0.00104 mg/l (nd)
marine water	0.000104 mg/l (nd)
STP	10 mg/l (nd)
sedim., dw, fre.wat.	1.06 mg/Kg (nd)
sedim., dw, mar.wat.	0.11 mg/Kg (nd)
soil,dw	0.31 mg/Kg (nd)

94-36-0 dibenzoyl peroxide

freshwater	0.00002 mg/l (nd)
marine water	0.000002 mg/l (nd)
STP	0.35 mg/l (nd)
sedim., dw, fre.wat.	0.013 mg/Kg (nd)
sedim., dw, mar.wat.	0.001 mg/Kg (nd)
soil,dw	0.003 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**

Keep away from foodstuffs, beverages and food.
 Instantly remove any soiled and impregnated garments.
 Do not eat or drink while working.
 The usual precautionary measures should be adhered to in handling the chemicals.
 Wash hands during breaks and at the end of the work.
 Avoid contact with the eyes and skin.

· **Breathing equipment:**

Use breathing protection against the effects of fumes/dust/aerosol.
 Filter A/P2.
 Use a mask with particle filter in case of dust generation.

· **Protection of hands:**

If skin contact cannot be avoided, protective gloves are recommended to avoid possible sensitization.
 Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
 chemical protection gloves are suitable, which are tested according to EN 374
 Check protective gloves prior to each use for their proper condition.
 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

· **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.
 Chloroprene rubber, CR

· **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.

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- **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:** Weak, characteristic
- **Odour threshold:** Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

- **Melting point/freezing point:** Not determined
- **Initial boiling point and boiling range:** Not determined

· **Flash point:** Not applicable

· **Inflammability (solid, gaseous)** May cause fire.

· **Decomposition temperature:** 55 °C (SADT)

· **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 applicable.

· **Density at 20 °C** 1.23 g/cm³

- **Settled apparent density** 640 kg/m³
- **Relative density** Not determined.
- **Vapour density** Not applicable.
- **Evaporation rate** Not applicable.

· **Solubility in / Miscibility with**

· **Water:** Insoluble

· **Partition coefficient: n-octanol/water:** Not determined.

· **Viscosity:**

- **dynamic:** Not applicable.
- **kinematic:** Not applicable.

· **9.2 Other information** No further relevant information available.

SECTION 10: Stability and reactivity

· **10.1 Reactivity** No further relevant information available.

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- **10.2 Chemical stability**
 - **Conditions to be avoided:**
 - Auto-catalytic thermal decomposition
 - Visible decomposition with spontaneous ignition on heating
 - Protect from heat and direct sunlight.
 - Keep ignition sources away - Do not smoke.
- **10.3 Possibility of hazardous reactions**
 - Reacts with reducing agents
 - Reacts with heavy metals
- **10.4 Conditions to avoid** Heat, flames and sparks.
- **10.5 Incompatible materials:**
 - metals
 - reducing agent
 - Radical initiator
 - Strong bases
 - Strong acids
- **10.6 Hazardous decomposition products:**
 - Benzol
 - Carbon dioxide

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:**

84-61-7 dicyclohexyl phthalate

Oral	LD50	>2,000 mg/kg (rat) (OECD 423)
Dermal	LD50	>2,000 mg/kg (rat) (OECD 402)

94-36-0 dibenzoyl peroxide

Oral	LD0	>2,000 mg/kg (mouse) (OECD 401)
Inhalative	LC0/4h	24.3 ppm (rat) (OECD 403)

- **Primary irritant effect:**
 - **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
 - **Serious eye damage/irritation**
 - Causes serious eye irritation.
 - **Respiratory or skin sensitisation**
 - May cause an allergic skin reaction.
- **Additional toxicological information:**
 - **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
 - Repr. 1B
 - **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**
 - May damage the unborn child.
 - **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.

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SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**

84-61-7 dicyclohexyl phthalate

EC50/21d	0.679 mg/L (daphnia) (OECD 211)
LC50/96h	>2 mg/l (fish) (OECD 203)
NOEC / 21d	0.181 mg/l (daphnia) (OECD 201)
ErC50 / 72 h	>2 mg/l (algae) (OECD 201)
NOEC / 72h	>2 mg/l (algae) (OECD 201)
NOEC / 48h	>2 mg/l (daphnia) (OECD 202)

94-36-0 dibenzoyl peroxide

EC50/72h	0.042 mg/l (algae) (OECD 201)
EC50/48h	0.11 mg/l (daphnia) (OECD 202)
LC50/96h	0.06 mg/l (fish) (OECD 203)
ErC50 / 72 h	0.071 mg/l (algae) (OECD 201)
NOEC / 72h	0.02 mg/l (algae) (OECD 201)
NOEC / 96h	0.032 mg/l (fish) (OECD 203)
NOEC / 48h	0.076 mg/l (daphnia) (OECD 202)
ErC10	0.001 mg/L /21d (daphnia) (OECD 211)

· **12.2 Persistence and degradability**

84-61-7 dicyclohexyl phthalate

Biodegradation	68.5 % /28d (nd)
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94-36-0 dibenzoyl peroxide

Biodegradation	71 % /28d (nd) (OECD 301D)
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· **12.3 Bioaccumulative potential** No further relevant information available.

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

· **Additional ecological information:**

· **General notes:**

Avoid transfer into the environment.

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** Disposal must be made according to official regulations.

· **Uncleaned packagings:**

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

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SECTION 14: Transport information

· 14.1 UN-Number · ADR, IMDG, IATA	UN3106
· 14.2 UN proper shipping name · ADR · IMDG · IATA	3106 ORGANIC PEROXIDE TYPE D, SOLID (dibenzoyl peroxide) ORGANIC PEROXIDE TYPE D, SOLID (dibenzoyl peroxide), MARINE POLLUTANT ORGANIC PEROXIDE TYPE D, SOLID (dibenzoyl peroxide)
· 14.3 Transport hazard class(es) · ADR	
	
· Class · Label	5.2 (P1) Organic peroxides. 5.2
· IMDG	
	
· Class · Label	5.2 Organic peroxides. 5.2
· IATA	
	
· Class · Label	5.2 Organic peroxides. 5.2
· 14.4 Packing group · ADR, IMDG, IATA	Void
· 14.5 Environmental hazards: · Marine pollutant: · Special marking (ADR):	Yes Symbol (fish and tree) Symbol (fish and tree)
· 14.6 Special precautions for user · Kemler Number: · EMS Number: · Stowage Category · Stowage Code	Warning: Organic peroxides. - F-J,S-R D SW1 Protected from sources of heat.

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· Segregation Code	SG35 Stow "separated from" SGG1-acids SG36 Stow "separated from" SGG18-alkalis.
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	-
· ADR	
· Limited quantities (LQ)	500 g
· Excepted quantities (EQ)	Code: E0 Not permitted as Excepted Quantity
· Transport category	2
· Tunnel restriction code	D
· IMDG	
· Limited quantities (LQ)	500 g
· Excepted quantities (EQ)	Code: E0 Not permitted as Excepted Quantity
· UN "Model Regulation":	UN 3106 ORGANIC PEROXIDE TYPE D, SOLID (DIBENZOYL PEROXIDE), 5.2

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.

· Seveso category

P6b SELF-REACTIVE SUBSTANCES AND MIXTURES and ORGANIC PEROXIDES

E1 Hazardous to the Aquatic Environment

· Qualifying quantity (tonnes) for the application of lower-tier requirements 50 t

· Qualifying quantity (tonnes) for the application of upper-tier requirements 200 t

· Information about limitation of use:

Employment restrictions concerning young persons must be observed.

Employment restrictions concerning women of child-bearing age must be observed.

· Other regulations, limitations and prohibitive regulations -

· Substances of very high concern (SVHC) according to REACH, Article 57

84-61-7 dicyclohexyl phthalate

· 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

H241 Heating may cause a fire or explosion.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H360D May damage the unborn child.

H400 Very toxic to aquatic life.

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H410 Very toxic to aquatic life with long lasting effects.

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

SVHC: Substances of Very High Concern

vPvB: very Persistent and very Bioaccumulative

Self-react. B: Self-reactive substances and mixtures – Type B

Org. Perox. B: Organic peroxides – Type B

Org. Perox. D: Organic peroxides – Type C/D

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

Repr. 1B: Reproductive toxicity – Category 1B

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term 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.**