

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

Printing date 03.07.2017

Version number 3

Revision: 26.06.2017

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

- **1.1 Product identifier**
 - **Trade name: Technovit 8100 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. 2 H361f Suspected of damaging fertility.
Aquatic Chronic 2 H411 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.
H361f Suspected of damaging fertility.
H411 Toxic to aquatic life with long lasting effects.
- **Precautionary statements**
P220 Keep away from reducing agents, heavy metal compounds, acids and alkalis.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P235 Keep cool.
P233 Keep container tightly closed.
P273 Avoid release to the environment.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

(Contd. on page 2)

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

Printing date 03.07.2017

Version number 3

Revision: 26.06.2017

Trade name: Technovit 8100 Hardener 1

(Contd. of page 1)

- **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: 94-36-0 EINECS: 202-327-6 Reg.nr.: 01-2119511472-50	dibenzoyl peroxide Self-react. B, H241; Org. Perox. B, H241; Aquatic Acute 1, H400; Eye Irrit. 2, H319; Skin Sens. 1, H317	25-50%
CAS: 84-61-7 EINECS: 201-545-9 Reg.nr.: 01-2119978223-34-XXXX	dicyclohexyl phthalate Repr. 2, H361; Skin Sens. 1, H317; Aquatic Chronic 3, H412	25-50%

- **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**
 - **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.
 - **After eye contact**
Rinse opened eye for several minutes under running water. Then consult doctor.
 - **After swallowing**
Rinse out mouth and then drink plenty of water.
In case of persistent symptoms consult doctor.
Seek immediate medical advice.
- **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.
- **5.2 Special hazards arising from the substance or mixture**
Formation of toxic gases is possible during heating or in case of fire.
- **5.3 Advice for firefighters**
 - **Protective equipment:** No special measures required.
 - **Additional information** -

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
Avoid causing dust.

(Contd. on page 3)

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

Printing date 03.07.2017

Version number 3

Revision: 26.06.2017

Trade name: Technovit 8100 Hardener 1

(Contd. of page 2)

- **6.2 Environmental precautions:** No special measures required.
- **6.3 Methods and material for containment and cleaning up:** Collect mechanically.
- **6.4 Reference to other sections**
 No dangerous materials are released.
 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.
 Keep containers tightly sealed.
 Prevent formation of dust.
 - **Information about protection against explosions and fires:** Protect from heat.
- **7.2 Conditions for safe storage, including any incompatibilities**
 - **Storage**
 - **Requirements to be met by storerooms and containers:** No special requirements.
 - **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:** None.
 - **Recommended storage temperature:** < 25 °C
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

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

· **8.1 Control parameters**

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

94-36-0 dibenzoyl peroxide

WEL Long-term value: 5 mg/m³

84-61-7 dicyclohexyl phthalate

WEL Long-term value: 5 mg/m³

· **DNELs**

94-36-0 dibenzoyl peroxide

Oral	ge.pop., l.te, syst.	1.65 mg/Kg (nd)
Dermal	worker industr., l.te., syst.	6.6 mg/Kg/d (nd)
	ge.pop., l.te, syst.	3.3 mg/Kg/d (nd)
Inhalative	worker industr., l.te., syst.	11.75 mg/m ³ (nd)
	ge.pop., l.te, syst.	2.9 mg/m ³ (nd)

84-61-7 dicyclohexyl phthalate

Dermal	worker industr., l.te., syst.	6.6 mg/Kg/d (nd)
Inhalative	worker industr., l.te., syst.	11.75 mg/m ³ (nd)

· **PNECs**

84-61-7 dicyclohexyl phthalate

freshwater	0.000602 mg/l (nd)
marine water	0.000602 mg/l (nd)
STP	0.35 mg/l (nd)
sedim., dw, fre.wat.	0.388 mg/Kg (nd)

(Contd. on page 4)

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

Printing date 03.07.2017

Version number 3

Revision: 26.06.2017

Trade name: Technovit 8100 Hardener 1

(Contd. of page 3)

- **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.
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 P1.*
 - **Protection of hands:**
*If skin contact cannot be avoided, protective gloves are recommended to avoid possible sensitization.
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.
 - **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.
 - **Eye protection:** *Safety glasses*
 - **Body protection:** *Light weight protective clothing*

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
 - **General Information**
 - **Appearance:**
 - **Form:** Powder
 - **Colour:** White
 - **Smell:** Weak, characteristic
 - **Odour threshold:** Not determined.
 - **pH-value:** Not applicable.
 - **Change in condition**
 - **Melting point/Melting range:** Not determined
 - **Boiling point/Boiling range:** Not determined
 - **Flash point:** Not applicable
 - **Inflammability (solid, gaseous)** May cause fire.
 - **Ignition temperature:** 380.0 °C
 - **Decomposition temperature:** 55 °C (SADT)
 - **Self-inflammability:** Product is not selfigniting.
 - **Danger of explosion:** Product is not explosive.

(Contd. on page 5)

GB

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

Printing date 03.07.2017

Version number 3

Revision: 26.06.2017

Trade name: Technovit 8100 Hardener 1

(Contd. of page 4)

· Critical values for explosion:	
· Lower:	Not determined.
· Upper:	Not determined.
· Steam pressure:	Not applicable.
· Density at 20 °C	1.23 g/cm ³
· 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.
- **10.2 Chemical stability**
 - **Conditions to be avoided:** Auto-catalytic thermal decomposition
- **10.3 Possibility of hazardous reactions**
 - Reacts with amines
 - Reacts with reducing agents
 - Reacts with heavy metals
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **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:**

94-36-0 dibenzoyl peroxide		
Oral	LD50	5000 mg/kg (rat)
Inhalative	LC50/4 h	24300 mg/l (rat)
84-61-7 dicyclohexyl phthalate		
Oral	LD50	30000 mg/kg (rat)

- **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.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)** Repr. 2
 - **Germ cell mutagenicity** Based on available data, the classification criteria are not met.

(Contd. on page 6)

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

Printing date 03.07.2017

Version number 3

Revision: 26.06.2017

Trade name: Technovit 8100 Hardener 1

(Contd. of page 5)

- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity**
 Suspected of damaging fertility.
- **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:**

94-36-0 dibenzoyl peroxide

EC50/72h	>2 mg/l (algae)
EC50/48h	>2 mg/l (daphnia)
LC50/96h	>2 mg/l (fish)

- **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.
 - **Additional ecological information:**
 - **General notes:** Avoid transfer into the environment.
- **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.

· **European waste catalogue**

11 01 98* | other wastes containing dangerous substances

- **Uncleaned packagings:**
 - **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

· **14.1 UN-Number**

· **ADR, IMDG, IATA** UN3106

· **14.2 UN proper shipping name**

· **ADR** 3106 ORGANIC PEROXIDE TYPE D, SOLID (Dibenzoyl peroxide 50 %)

· **IMDG** ORGANIC PEROXIDE TYPE D, SOLID (Dibenzoyl peroxide 50 %), MARINE POLLUTANT

· **IATA** ORGANIC PEROXIDE TYPE D, SOLID (Dibenzoyl peroxide 50 %)

(Contd. on page 7)

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

Printing date 03.07.2017

Version number 3

Revision: 26.06.2017

Trade name: Technovit 8100 Hardener 1

(Contd. of page 6)

14.3 Transport hazard class(es)

· ADR



· **Class** 5.2 (P1) Organic peroxides.
· **Label** 5.2

· IMDG



· **Class** 5.2 Organic peroxides.
· **Label** 5.2

· IATA



· **Class** 5.2 Organic peroxides.
· **Label** 5.2

14.4 Packing group
· ADR, IMDG, IATA

Void

14.5 Environmental hazards:

· **Marine pollutant:** Yes
Symbol (fish and tree)
· **Special marking (ADR):** Symbol (fish and tree)

14.6 Special precautions for user

Warning: Organic peroxides.

· **Kemler Number:** -
· **EMS Number:** F-J,S-R

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

(Contd. on page 8)

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

Printing date 03.07.2017

Version number 3

Revision: 26.06.2017

Trade name: Technovit 8100 Hardener 1

(Contd. of page 7)

· **UN "Model Regulation":** UN3106, ORGANIC PEROXIDE TYPE D, SOLID (Dibenzoyl peroxide 50 %), 5.2

SECTION 15: Regulatory information

· **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **National regulations**

· **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 -**

· **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.

H361 Suspected of damaging fertility or the unborn child.

H400 Very toxic to aquatic life.

H412 Harmful to aquatic life with long lasting effects.

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport 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

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. 2: Reproductive toxicity – Category 2

Repr. 2: Reproductive toxicity – Category 2

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

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

· *** Data compared to the previous version altered.**