

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

Printing date 16.06.2021

Version number 5

Revision: 16.06.2021

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

- **1.1 Product identifier**
 - Trade name: **Technovit Provil/ Technovit Provil Light**
- **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 indirect surface testing and impressions
- **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**
STOT RE 1 H372 Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.
 - **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**
- 

GHS08
- **Signal word** Danger
 - **Hazard-determining components of labelling:**
Cristobalite
 - **Hazard statements**
H372 Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.
 - **Precautionary statements**
P260 Do not breathe dust/fume/gas/mist/vapours/spray.
P284 In case of inadequate ventilation wear respiratory protection.
P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.
 - **2.3 Other hazards**
 - **Results of PBT and vPvB assessment**

· PBT:	
556-67-2	octamethylcyclotetrasiloxane
· vPvB:	
556-67-2	octamethylcyclotetrasiloxane

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SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures

· **Description:** -

· **Dangerous components:**

CAS: 14464-46-1 EINECS: 238-878-4	Cristobalite	STOT RE 1, H372	25-50%
CAS: 556-67-2 EINECS: 209-136-7 Reg.nr.: 01-2119529238-36-xxxx	octamethylcyclotetrasiloxane	Flam. Liq. 3, H226 Repr. 2, H361f Aquatic Chronic 4, H413 PBT; vPvB	<1%

· **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 into the open air.

In case of irregular breathing or respiratory arrest provide artificial respiration.

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

· **After inhalation**

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

Take affected persons into the open air and position comfortably

Supply fresh air or oxygen; call for doctor.

· **After skin contact** 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**

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

Breathing difficulty

Coughing

4.3 Indication of any immediate medical attention and special treatment needed

Subsequent observation for pneumonia and pulmonary oedema

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)

5.3 Advice for firefighters

· **Protective equipment:**

Wear self-contained breathing apparatus.

(EN 133)

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SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Use breathing protection against the effects of fumes/dust/aerosol.
Ensure adequate ventilation
Wear protective equipment. Keep unprotected persons away.
Do not breathe vapor / mist / gas.
- **6.2 Environmental precautions:**
Do not allow to enter the ground/soil.
Do not allow to enter drainage system, surface or ground water.
Damp down gases/fumes/haze with water spray jet.
If material reaches soil inform authorities responsible for such cases.
- **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**
Prevent formation of aerosols.
Avoid contact with eyes and skin.
Do not breathe vapor / mist / gas.
Ensure good ventilation/exhaustion at the workplace.
 - **Handling**
do not mix with
Strong acids
Strong bases
metals
Strong oxidizers
 - **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, dry place in tightly closed containers.
 - **Information about storage in one common storage facility:** Store away from foodstuffs.
 - **Further information about storage conditions:** Store in a cool place.
- **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:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
Not required.

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· **DNELs****556-67-2 octamethylcyclotetrasiloxane**

Oral	ge.pop., l.te, syst.	3.7 mg/Kg (nd)
Inhalative	worker industr., l.te., syst.	73 mg/m ³ (nd)
	worker industr., l.te., local	73 mg/m ³ (nd)
	ge.pop., l.te, syst.	13 mg/m ³ (nd)
	ge.pop., l.te, local	13 mg/m ³ (nd)

· **PNECs****556-67-2 octamethylcyclotetrasiloxane**

freshwater	0.0015 mg/l (nd)
marine water	0.00015 mg/l (nd)
STP	10 mg/l (nd)
sedim., dw, fre.wat.	3 mg/Kg (nd)
sedim., dw, mar.wat.	0.3 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**

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

Do not eat or drink while working.

Do not inhale dust / smoke / mist.

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

· **Breathing equipment:**

Use breathing protection in case of insufficient ventilation.

ABEK-P3 (EN14387)

· **Protection of hands:**

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

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.

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.

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SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
 - **General Information**
 - **Appearance:**
 - **Form:** Pasty
 - **Colour:** According to product specification
 - **Smell:** Odourless
 - **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.
 - **Critical values for explosion:**
 - **Lower:** Not determined.
 - **Upper:** Not determined.
 - **Steam pressure:** Not determined.
 - **Density at 20 °C** 1.6 g/cm³
 - **Relative density** Not determined.
 - **Vapour density** Not determined.
 - **Evaporation rate** Not determined.
 - **Solubility in / Miscibility with**
 - **Water:** Not miscible or difficult to mix
 - **Partition coefficient: n-octanol/water:** Not determined.
 - **Viscosity:**
 - **dynamic:** Not determined.
 - **kinematic:** Not determined.
- **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:** 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 acids
 - Strong bases
 - metals
 - Strong oxidizers

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· **10.6 Hazardous decomposition products:** None

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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:**

556-67-2 octamethylcyclotetrasiloxane

Oral	LD50	>4,800 mg/kg (rat) (OECD 401)
Dermal	LD50	>2,375 mg/kg (rat) (OECD 402)
Inhalative	LC50/4 h	36 mg/l (rat) (OECD 403)

· **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.

· **Respiratory or skin sensitisation**

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

· **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**

Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

· **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**

556-67-2 octamethylcyclotetrasiloxane

EC50/21d	>0.015 mg/L (daphnia) (EPA OTS 797.1330)
EC50/48h	>0.015 mg/l (daphnia) (EPA OTS 797.1300)
LC50/96h	>0.022 mg/l (fish) (EPA OTS 797.1400)
NOEC / 91d	≥0.0044 mg/l (fish)
NOEC / 21d	≥0.015 mg/l (daphnia) (EPA OTS 797.1330)
NOEC / 96h	<0.022 mg/l (algae) (EPA OTS 797.1050)
	≥0.022 mg/l (fish) (EPA OTS 797.1400)
NOEC / 48h	≥0.015 mg/l (daphnia) (EPA OTS 797.1300)
ErC50/ 96h	>0.022 mg/L (algae) (EPA OTS 797.1050)

· **12.2 Persistence and degradability**

556-67-2 octamethylcyclotetrasiloxane

Biodegradation	3.7 % /29d (nd) (OECD 310)
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· **12.3 Bioaccumulative potential**

556-67-2 octamethylcyclotetrasiloxane

Bloconcentration factor (BCF)	12,400 (nd)
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- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
 - **General notes:**
 - Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.
 - 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:	
556-67-2	octamethylcyclotetrasiloxane
· vPvB:	
556-67-2	octamethylcyclotetrasiloxane
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
 - **Recommendation** Smaller quantities can be disposed with household garbage.
- **Uncleaned packagings:**
 - **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- | | |
|--|-----------------|
| · 14.1 UN-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 Transport in bulk according to Annex II of Marpol and the IBC Code | 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.
- **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**
 - H226 Flammable liquid and vapour.
 - H361f Suspected of damaging fertility.
 - H372 Causes damage to organs through prolonged or repeated exposure.
 - H413 May cause long lasting harmful effects to aquatic life.
- **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
 - Flam. Liq. 3: Flammable liquids – Category 3
 - Repr. 2: Reproductive toxicity – Category 2
 - STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1
 - Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4
- **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.**

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