

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

Printing date 16.05.2022

Version number 3 (replaces version 2)

Revision: 16.05.2022

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

- **1.1 Product identifier**
 - Trade name: **Technovit Provil Putty**
- **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.
 - Aquatic Chronic 3 H412 Harmful 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 GB 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.
 H412 Harmful to aquatic life with long lasting effects.
- **Precautionary statements**
 P260 Do not breathe dust/fume/gas/mist/vapours/spray.
 P273 Avoid release to the environment.
 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
541-02-6	Decamethylcyclopentasiloxane
540-97-6	Dodecamethylcyclohexasiloxane

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· vPvB:	
556-67-2	octamethylcyclotetrasiloxane
541-02-6	Decamethylcyclopentasiloxane
540-97-6	Dodecamethylcyclohexasiloxane

SECTION 3: Composition/information on ingredients

· **3.2 Mixtures**

· **Description: -**

· **Dangerous components:**

CAS: 14464-46-1 EINECS: 238-455-4	crystalite 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 1, H410 (M=10) PBT; vPvB	≥0.025-<0.25%
CAS: 541-02-6 EINECS: 208-764-9 Reg.nr.: 01-2119511367-43-xxxx	Decamethylcyclopentasiloxane Non-classified vPvB substance. Non-classified PBT substance. Substance identified as having endocrine disrupting properties (II).	<1%
CAS: 540-97-6 EINECS: 208-762-8 Reg.nr.: 01-2119717435-42-xxxx	Dodecamethylcyclohexasiloxane Non-classified vPvB substance. Non-classified PBT substance. Substance identified as having endocrine disrupting properties (II).	<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**

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**

Breathing difficulty

Coughing

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- **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)
 - **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**
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.
Inform respective authorities in case product reaches water or sewage system.
- **6.3 Methods and material for containment and cleaning up:**
Dispose of the material collected according to regulations.
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**
Prevent formation of aerosols.
Avoid contact with eyes and skin.
Do not breathe vapor / mist / gas.
Ensure good ventilation/exhaustion at the workplace.
 - **Information about protection against explosions and fires:**
Protect from heat.
Keep ignition sources away - Do not smoke.

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· **Handling**

do not mix with
 Strong acids
 Strong bases
 Strong oxidizers
 metals

· **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**

· **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.

· **DNELs**

556-67-2 octamethylcyclotetrasiloxane

Oral Inhalative	general population, long term, systemic	3.7 mg/Kg (not defined)
	worker industrial, long term, systemic	73 mg/m3 (not defined)
	worker industrial, long term, local	73 mg/m3 (not defined)
	general population, long term, systemic	13 mg/m3 (not defined)
	general population, long term, local	13 mg/m3 (not defined)

541-02-6 Decamethylcyclopentasiloxane

Oral Inhalative	general population, long term, systemic	5 mg/Kg (not defined)
	worker industrial, long term, systemic	97.3 mg/m3 (not defined)
	worker industrial, long term, local	24.2 mg/m3 (not defined)
	general population, long term, systemic	17.3 mg/m3 (not defined)
	general population, long term, local	4.3 mg/m3 (not defined)

540-97-6 Dodecamethylcyclohexasiloxane

Oral Inhalative	general population, acute, systemic	1.7 mg/Kg (not defined)
	general population, long term, systemic	1.7 mg/Kg (not defined)
	worker industrial, acute, local	6.1 mg/m3 (not defined)
	worker industrial, long term, systemic	11 mg/m3 (not defined)
	worker industrial, long term, local	1.22 mg/m3 (not defined)
	general population, acute, local	1.5 mg/m3 (not defined)
	general population, long term, systemic	2.7 mg/m3 (not defined)
	general population, long term, local	0.3 mg/m3 (not defined)

· **PNECs**

556-67-2 octamethylcyclotetrasiloxane

freshwater	0.0015 mg/l (not defined)
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marine water	0.00015 mg/l (not defined)
sewage treatment plant	10 mg/l (not defined)
sediment, dry weight, freshwater	3 mg/Kg (not defined)
sediment, dry weight, marine water	0.3 mg/Kg (not defined)
541-02-6 Decamethylcyclpentasiloxane	
freshwater	0.0012 mg/l (not defined)
marine water	0.00012 mg/l (not defined)
sewage treatment plant	10 mg/l (not defined)
sediment, dry weight, freshwater	11 mg/Kg (not defined)
sediment, dry weight, marine water	1.1 mg/Kg (not defined)
540-97-6 Dodecamethylcyclohexasiloxane	
sewage treatment plant	1 mg/l (not defined)
sediment, dry weight, freshwater	13.5 mg/Kg (not defined)
sediment, dry weight, marine water	1.35 mg/Kg (not defined)

· **Additional information:** The lists that were valid during the compilation were used as basis.

· **8.2 Exposure controls**

· **Individual protection measures, such as personal protective equipment**

· **General protective and hygienic measures**

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

Do not eat or drink while working.

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

Do not inhale dust / smoke / mist.

· **Breathing equipment:**

Use breathing protection in case of insufficient ventilation.

filter: ABEK

· **Hand protection**

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

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

· **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 through 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.

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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

- **Physical state** Fluid
- **Colour:** Blue
- **Smell:** Odourless
 - **Odour threshold:** Not determined.
- **Melting point/freezing point:** Not determined
- **Boiling point or initial boiling point and boiling range** 175 °C (556-67-2 octamethylcyclotetrasiloxane)
- **Flammability** Not applicable.
- **Lower and upper explosion limit**
 - **Lower:** Not determined.
 - **Upper:** Not determined.
- **Flash point:** 51 °C (556-67-2 octamethylcyclotetrasiloxane)
- **Ignition temperature:** 368 °C (540 - 97 - 6 Dodecamethylcyclohexasiloxane)
- **Decomposition temperature:** Not determined.
- **SADT** Not determined.
- **pH** Not determined.
- **Viscosity:**
 - **Kinematic viscosity** Not determined.
 - **dynamic:** Not determined.
- **Solubility**
 - **Water:** Not miscible or difficult to mix
- **Partition coefficient n-octanol/water (log value)** Not determined.
- **Steam pressure at 25 °C:** 1.3 hPa (556 - 67 - 2 octamethylcyclotetrasiloxane)
- **Density and/or relative density**
 - **Density** Not determined
 - **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.
Not determined.
- **Change in condition**
 - **Evaporation rate** Not determined.

· Information with regard to physical hazard classes

- **Explosives** Void
- **Flammable gases** Void
- **Aerosols** Void
- **Oxidising gases** Void

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· 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 acids
 - Strong bases
 - Strong oxidizers
 - metals
- **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.

· **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)

541-02-6 Decamethylcyclopentasiloxane

Oral	LD50	>5,000 mg/kg (rat) (OECD 401)
Dermal	LD50	>2,000 mg/kg (rab) (OECD 402)

540-97-6 Dodecamethylcyclohexasiloxane

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

- **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.
- **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.

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- **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.
- **11.2 Information on other hazards**

· **Endocrine disrupting properties**

556-67-2	octamethylcyclotetrasiloxane	List II, III
541-02-6	Decamethylcyclopentasiloxane	List II
540-97-6	Dodecamethylcyclohexasiloxane	List II

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)

541-02-6 Decamethylcyclopentasiloxane

EC50/21d	>0.015 mg/L (daphnia) (OECD 211)
EC50/48h	>0.0029 mg/l (daphnia) (OECD 202)
LC50/96h	>0.016 mg/l (fish) (OECD 204)
NOEC / 91d	≥0.014 mg/l (fish) (OECD 210)
NOEC / 21d	>0.0015 mg/l (daphnia) (OECD 211)
NOEC / 96h	≥0.012 mg/l (algae) (OECD 201) ≥0.016 mg/l (fish) (OECD 204)
NOEC / 48h	≥0.0029 mg/l (daphnia) (OECD 202)
EC50/96h	>0.012 mg/L (algae) (OECD 201)

540-97-6 Dodecamethylcyclohexasiloxane

NOEC / 91d	≥0.014 mg/l (fish) (OECD 210)
NOEC / 21d	0.0046 mg/l (daphnia) (OECD 211)
ErC50 / 72 h	>0.002 mg/l (algae) (OECD 201)
NOEC / 72h	≥0.002 mg/l (algae) (OECD 201)

· **12.2 Persistence and degradability**

556-67-2 octamethylcyclotetrasiloxane

Biodegradation	3.7 % /29d (not defined) (OECD 310)
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541-02-6 Decamethylcyclopentasiloxane

Biodegradation	0.14 % /28d (not defined) (OECD 310)
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540-97-6 Dodecamethylcyclohexasiloxane

Biodegradation 4.47 % /28d (not defined) (OECD 310)

· 12.3 Bioaccumulative potential

556-67-2 octamethylcyclotetrasiloxane

Bloconcentration factor (BCF) 12,400 (not defined)

541-02-6 Decamethylcyclopentasiloxane

Bloconcentration factor (BCF) 7,060 (fish)
 7,060 (not defined)

540-97-6 Dodecamethylcyclohexasiloxane

Bloconcentration factor (BCF) 1,160 (not defined)

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

· 12.5 Results of PBT and vPvB assessment

· PBT:

556-67-2	octamethylcyclotetrasiloxane
541-02-6	Decamethylcyclopentasiloxane
540-97-6	Dodecamethylcyclohexasiloxane

· vPvB:

556-67-2	octamethylcyclotetrasiloxane
541-02-6	Decamethylcyclopentasiloxane
540-97-6	Dodecamethylcyclohexasiloxane

· 12.6 Endocrine disrupting properties

For information on endocrine disrupting properties see section 11.

· 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

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

Disposal must be made according to official regulations.

· Uncleaned packagings:

· Recommendation:

Disposal must be made according to official regulations.
 Non contaminated packagings can be used for recycling.

SECTION 14: Transport information

· 14.1 UN number or ID number

· ADR, IMDG, IATA Void

· 14.2 UN proper shipping name

· ADR, IMDG, IATA Void

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· 14.3 Transport hazard class(es)	
· ADR, ADN, IMDG, IATA	
· Class	Void
· 14.4 Packing group	
· ADR, IMDG, IATA	Void
· 14.5 Environmental hazards:	Not applicable.
· 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**
 - **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.
- H410 Very toxic to aquatic life with long lasting effects.

· **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)
- DNEL: Derived No-Effect Level (GB REACH)
- PNEC: Predicted No-Effect Concentration (GB 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 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1
- Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

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· Sources*(EC) 1272/2008: classification, labelling and packaging of substances and mixtures**(EC) 1907/2006: GB 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.**

GB