



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

Printing date 08.02.2023

Version number 6 (replaces version 5)

Revision: 08.02.2023

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

- **1.1 Product identifier**
  - Trade name: **Provil Novo Medium Cat, Provil Novo Medium CD2 regular Cat., Provil Novo Medium CD 2 fast set Cat.**
- **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** Dental impression material
- **1.3 Details of the supplier of the safety data sheet**
  - **Manufacturer/Supplier:**  
Kulzer GmbH  
Leipziger Straße 2, 63450 Hanau (Germany) Tel.: +49 (0)800 4372522
  - **Informing department:** E-Mail: [msds@kulzer-dental.com](mailto:msds@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**  
The product is not classified, according to the CLP regulation.
  - **Additional information:**  
Since the product is a medical device in the sense of Directive 93/42/EEC (MDD) or the Regulation (EU) 2017/745 (MDR), that is intended for the end user and is used invasively or with physical contact, it is exempted from the classification and labeling obligation according to Regulation (EC) 1272/2008.
- **2.2 Label elements**
  - **Labelling according to Regulation (EC) No 1272/2008** Void
    - **Hazard pictograms** Void
    - **Signal word** Void
    - **Hazard statements** Void
  - **Additional information:** see 2.1
- **2.3 Other hazards -**
  - **Results of PBT and vPvB assessment**

· <b>PBT:</b>		
556-67-2	octamethylcyclotetrasiloxane	
· <b>vPvB:</b>		
556-67-2	octamethylcyclotetrasiloxane	
· <b>Determination of endocrine-disrupting properties</b>		
556-67-2	octamethylcyclotetrasiloxane	List II, III

**SECTION 3: Composition/information on ingredients**

- **3.2 Mixtures**
  - **Description:** -

· <b>Dangerous components:</b>		
CAS: 14464-46-1 EINECS: 238-878-4	Cristobalite STOT RE 1, H372	50-75%
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%

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· **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** 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.
- **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**  
CO<sub>2</sub>, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.  
Use fire fighting measures that suit the environment.
- **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:** Put on breathing apparatus.
  - **Additional information** -

#### **SECTION 6: Accidental release measures**

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Ensure adequate ventilation  
Avoid contact with eyes and skin.
- **6.2 Environmental precautions:** Prevent material from reaching sewage system, holes and cellars.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).
- **6.4 Reference to other sections**  
No dangerous materials are released.  
See Section 7 for information on safe handling  
See Section 8 for information on personal protection equipment.  
See Section 13 for information on disposal.  
-

#### **SECTION 7: Handling and storage**

- **7.1 Precautions for safe handling**  
Keep containers tightly sealed.  
Ensure good ventilation/exhaustion at the workplace.
  - **Information about protection against explosions and fires:** No special measures required.

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- **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:** Not required.
    - **Further information about storage conditions:** None.
- **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:**

**14464-46-1 Cristobalite**

OEL (Ireland) Long-term value: 0.1 mg/m<sup>3</sup>

· **DNELs**

**556-67-2 octamethylcyclotetrasiloxane**

Oral	general population, long term, systemic	3.7 mg/Kg (not defined)
Inhalative	worker industrial, long term, systemic	73 mg/m <sup>3</sup> (not defined)
	worker industrial, long term, local	73 mg/m <sup>3</sup> (not defined)
	general population, long term, systemic	13 mg/m <sup>3</sup> (not defined)
	general population, long term, local	13 mg/m <sup>3</sup> (not defined)

· **PNECs**

**556-67-2 octamethylcyclotetrasiloxane**

freshwater	0.0015 mg/l (not defined)
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)

· **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.  
Wash hands during breaks and at the end of the work.
  - **Breathing equipment:** Not necessary if room is well-ventilated.
  - **Hand protection**  
Check protective gloves prior to each use for their proper condition.  
recommended
    - **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.

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- **For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:**
  - Butyl rubber, BR
  - Nitrile rubber, NBR
- **Eye/face 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**

- **Physical state** Fluid
- **Colour:** Light grey
- **Smell:** Characteristic
  - **Odour threshold:** Not determined.
- **Melting point/freezing point:** Not determined
- **Boiling point or initial boiling point and boiling range** >300 °C
- **Flammability** Not applicable.
- **Lower and upper explosion limit**
  - **Lower:** Not determined.
  - **Upper:** Not determined.
- **Flash point:** >130 °C
- **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:** Not determined.
- **Density and/or relative density**
  - **Density at 20 °C** 1.41-1.43 g/cm<sup>3</sup>
  - **Relative density** Not determined.
  - **Vapour density** Not determined.

**9.2 Other information**

No further relevant information available.

- **Appearance:**
  - **Form:** Pasty
- **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.

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**· Information with regard to physical hazard classes**

· <b>Explosives</b>	Void
	Void
· <b>Flammable gases</b>	Void
	Void
· <b>Aerosols</b>	Void
	Void
· <b>Oxidising gases</b>	Void
	Void
· <b>Gases under pressure</b>	Void
	Void
· <b>Flammable liquids</b>	Void
	Void
· <b>Flammable solids</b>	Void
	Void
· <b>Self-reactive substances and mixtures</b>	Void
	Void
· <b>Pyrophoric liquids</b>	Void
	Void
· <b>Pyrophoric solids</b>	Void
	Void
· <b>Self-heating substances and mixtures</b>	Void
	Void
· <b>Substances and mixtures, which emit flammable gases in contact with water</b>	Void
	Void
· <b>Oxidising liquids</b>	Void
	Void
· <b>Oxidising solids</b>	Void
	Void
· <b>Organic peroxides</b>	Void
	Void
· <b>Corrosive to metals</b>	Void
	Void
· <b>Desensitised explosives</b>	Void
	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** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** None
  - **Additional information:** -

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**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	>4800 mg/kg (rat) (OECD 401)
Dermal	LD50	>2375 mg/kg (rat) (OECD 402)
Inhalative	LC50/4 h	36 mg/l (rat) (OECD 403)

- **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.
- **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.

· **11.2 Information on other hazards**

· **Endocrine disrupting properties**

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

· **12.2 Persistence and degradability**

**556-67-2 octamethylcyclotetrasiloxane**

Biodegradation	3.7 % /29d (not defined) (OECD 310)
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· **12.3 Bioaccumulative potential**

**556-67-2 octamethylcyclotetrasiloxane**

Bloconcentration factor (BCF)	12400 (not defined)
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· **12.4 Mobility in soil** No further relevant information available.

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· **12.5 Results of PBT and vPvB assessment**

· **PBT:**

556-67-2 octamethylcyclotetrasiloxane

· **vPvB:**

556-67-2 octamethylcyclotetrasiloxane

· **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 undiluted product or large quantities of it to reach ground water, water bodies or sewage system.

**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

· **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 according to IMO instruments**

Not applicable.

· **Transport/Additional information:**

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· **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.
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 200 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 500 t
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 70

· **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients is listed.

· **REGULATION (EU) 2019/1148**

· **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

no information available

· **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

no information available

· **Regulation (EC) No 273/2004 on drug precursors**

None of the ingredients is listed.

· **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

None of the ingredients is listed.

· **REGULATION (EC) No 1005/2009 on substances that deplete the ozone layer – ANNEX I (Ozone-depleting potential)**

· **Other regulations, limitations and prohibitive regulations**

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

556-67-2 | octamethylcyclotetrasiloxane

· **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.

· **Date of previous version:** 28.06.2021

· **Version number of previous version:** 5

· **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)

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

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