



**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 Monophase CD2 regular Base, Provil Novo Monophase CD2 fast Base**

· **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

· **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**

· **PBT:**

556-67-2 | octamethylcyclotetrasiloxane

· **vPvB:**

556-67-2 | octamethylcyclotetrasiloxane

SECTION 3: Composition/information on ingredients

· **3.2 Mixtures**

· **Description:** -

· **Dangerous components:**

CAS: 14464-46-1 EINECS: 238-878-4	Cristobalite STOT RE 1, H372	50-75%
CAS: 78330-21-9	Alkohole, C11-14-iso-, C13-reich, ethoxyliert Eye Dam. 1, H318	≥1-<3%
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**
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.
- **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.
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.
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SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
Please observe the additional instructions in the product's instructions for use.
Keep containers tightly sealed.

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Ensure good ventilation/exhaustion at the workplace.

· **Information about protection against explosions and fires:** No special measures required.

· **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/m³

· **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 ³ (not defined)
	worker industrial, long term, local	73 mg/m ³ (not defined)
	general population, long term, systemic	13 mg/m ³ (not defined)
	general population, long term, local	13 mg/m ³ (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.

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- **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.
- **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** Tightly sealed 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: | Blue |
| | Light blue |
| · 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 | |
| · 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 | 1.44-1.45 g/cm ³ |
| · 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.

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· Change in condition	
· Evaporation rate	Not determined.
· Information with regard to physical hazard classes	
· Explosives	Void
	Void
· Flammable gases	Void
	Void
· Aerosols	Void
	Void
· Oxidising gases	Void
	Void
· Gases under pressure	Void
	Void
· Flammable liquids	Void
	Void
· Flammable solids	Void
	Void
· Self-reactive substances and mixtures	Void
	Void
· Pyrophoric liquids	Void
	Void
· Pyrophoric solids	Void
	Void
· Self-heating substances and mixtures	Void
	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
	Void
· Oxidising liquids	Void
	Void
· Oxidising solids	Void
	Void
· Organic peroxides	Void
	Void
· Corrosive to metals	Void
	Void
· Desensitised explosives	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

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· **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:**

78330-21-9 Alkohole, C11-14-iso-, C13-reich, ethoxyliert

Oral	LD50	7,400 mg/kg (rat)
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556-67-2 octamethylcyclotetrasiloxane

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

None of the ingredients is listed.

SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**

78330-21-9 Alkohole, C11-14-iso-, C13-reich, ethoxyliert

EC50/72h	2-10 mg/l (algae)
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EC50/48h	2-10 mg/l (daphnia)
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LC50/96h	5.6 mg/l (fish)
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556-67-2 octamethylcyclotetrasiloxane

EC50/21d	>0.015 mg/L (daphnia) (EPA OTS 797.1330)
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EC50/48h	>0.015 mg/l (daphnia) (EPA OTS 797.1300)
----------	--

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

ErC50/ 96h	>0.022 mg/L (algae) (EPA OTS 797.1050)
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· 12.2 Persistence and degradability**556-67-2 octamethylcyclotetrasiloxane**

Biodegradation 3.7 % /29d (not defined) (OECD 310)

· 12.3 Bioaccumulative potential**556-67-2 octamethylcyclotetrasiloxane**

Bioconcentration factor (BCF) 12,400 (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

· 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.

· European waste catalogue

18 01 06* chemicals consisting of or containing hazardous substances

· 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

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- | | |
|---|-----------------|
| · 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: | - |
| · 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 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.

H318 Causes serious eye damage.

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.

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- **Date of previous version:** 22.11.2021
- **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)
 - 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
 - Eye Dam. 1: Serious eye damage/eye irritation – Category 1
 - 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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