



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

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

· **1.1 Product identifier**

· Trade name: **Provil novo (base + cat)**

· -

Putty, Putty soft, Dynamix Putty, Monophase, Medium, Light (regular set, fast set)

· **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.

· **2.2 Label elements**

· **Labelling according to Regulation (EC) No 1272/2008** Void

· **Hazard pictograms** Void

· **Signal word** Void

· **Hazard statements** Void

· **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:**

2-component silicone impression material comprising base paste and matching catalyst paste for addition curing

· **Dangerous components:** Void

· **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** No special measures required.

· **After inhalation** Supply fresh air; consult doctor in case of symptoms.

· **After skin contact** Instantly wash with water and soap and rinse thoroughly.

· **After eye contact** Rinse opened eye for several minutes under running water.

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- **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** No further relevant information available.
- **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** Not required.
- **6.2 Environmental precautions:** No special measures required.
- **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 8 for information on personal protection equipment.
- 

**SECTION 7: Handling and storage**

- **7.1 Precautions for safe handling** No special measures required.
  - **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**

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

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**· 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.

· **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.

· **Breathing equipment:** Not required.

**· Protection of hands:**

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.

**· 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 protection:** not absolutely necessary

· **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:**

Pasty

· **Colour:**

According to product specification

· **Smell:**

Odourless

· **Odour threshold:**

Not determined.

· **pH-value:**

Not determined.

**· Change in condition**

· **Melting point/Melting range:**

Not determined

· **Boiling point/Boiling range:**

Not determined

· **Flash point:**

> 200 °C

· **Inflammability (solid, gaseous)**

Not applicable.

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· <b>Ignition temperature:</b>	
· <b>Decomposition temperature:</b>	Not determined.
· <b>Self-inflammability:</b>	Product is not selfigniting.
· <b>Danger of explosion:</b>	Product is not explosive.
· <b>Critical values for explosion:</b>	
· <b>Lower:</b>	Not determined.
· <b>Upper:</b>	Not determined.
· <b>Steam pressure at 20 °C:</b>	18 hPa
· <b>Density at 20 °C</b>	1.600 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with</b>	
· <b>Water:</b>	Not miscible or difficult to mix
· <b>Partition coefficient (n-octanol/water):</b>	Not determined.
· <b>Viscosity:</b>	
· <b>dynamic:</b>	Not determined.
· <b>kinematic:</b>	Not determined.
· <b>Solvent content:</b>	
· <b>VOC EU</b>	g/l
· <b>Solids content:</b>	44.8 %
· <b>9.2 Other information</b>	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** 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:**

**Polydimethylsiloxan, vinylendgestoppt**

Oral | LD50 | > 5000 mg/kg (rat)

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- **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.
- **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** 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:** No further relevant information available.
- **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:**  
Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.
- **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** Smaller quantities can be disposed with household garbage.
- **European waste catalogue**

18 01 07	chemicals other than those mentioned in 18 01 06
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- **Uncleaned packagings:**
  - **Recommendation:** Disposal must be made according to official regulations.

\* **SECTION 14: Transport information**

- |                                       |      |
|---------------------------------------|------|
| · <b>14.1 UN-Number</b>               |      |
| · <b>ADR, ADN, IMDG, IATA</b>         | Void |
| · <b>14.2 UN proper shipping name</b> |      |
| · <b>ADR, ADN, IMDG, IATA</b>         | Void |

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|--|-----------------|
| · <b>14.3 Transport hazard class(es)</b>   |                 |
| · <b>ADR, ADN, IMDG, IATA</b>  |                 |
| · <b>Class</b>   | Void            |
| · <b>14.4 Packing group</b>  |                 |
| · <b>ADR, IMDG, IATA</b>   | Void            |
| · <b>14.5 Environmental hazards:</b>   |                 |
| · <b>Marine pollutant:</b>   | No              |
| · <b>14.6 Special precautions for user</b>                                       | Not applicable. |
| · <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b> | Not applicable. |
| · <b>Transport/Additional information:</b>                                       | -               |
| · <b>UN "Model Regulation":</b>  | Void            |

**SECTION 15: Regulatory information**

- **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.

· **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)
- VOCV: Lenkungsabgabe auf flüchtigen organischen Verbindungen, Schweiz (Swiss Ordinance on volatile organic compounds)
- LC50: Lethal concentration, 50 percent
- LD50: Lethal dose, 50 percent
- PBT: Persistent, Bioaccumulative and Toxic
- vPvB: very Persistent and very Bioaccumulative

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