



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

Printing date 10.06.2021

Version number 4

Revision: 11.03.2021

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

- **1.1 Product identifier**
  - Trade name: **Provil Novo Putty fast Cat., Provil Novo Soft Putty fast 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**  
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**
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GHS08
- **Signal word** *Danger*
  - **Hazard-determining components of labelling:**  
*crystalite*
  - **Hazard statements**  
*H372 Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.*
  - **Precautionary statements**  
*P202 Do not handle until all safety precautions have been read and understood.*  
*P260 Do not breathe dust/fume/gas/mist/vapours/spray.*  
*P280 Wear protective gloves/protective clothing/eye protection/face protection.*  
*P314 Get medical advice/attention if you feel unwell.*
- **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:** -

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**· Dangerous components:**

CAS: 14464-46-1	cristobalite	STOT RE 1, H372	50-75%
EINECS: 238-455-4			

**· 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**

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**

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**  
Store in cool, dry place in tightly closed containers.  
No special precautions necessary if used correctly.
  - **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**
  - **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.
    - **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**  
Wash hands during breaks and at the end of the work.
    - **Breathing equipment:** Not necessary if room is well-ventilated.
    - **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:** 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**
    - **Appearance:**
      - **Form:** Pasty

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· <b>Colour:</b>	Light grey
· <b>Smell:</b>	Characteristic
· <b>Odour threshold:</b>	Not determined.
· <b>pH-value:</b>	Not determined.
· <b>Change in condition</b>	
· <b>Melting point/freezing point:</b>	Not determined
· <b>Initial boiling point and boiling range:</b>	Not determined
· <b>Flash point:</b>	Not applicable
· <b>Inflammability (solid, gaseous)</b>	Not applicable.
· <b>Decomposition temperature:</b>	Not determined.
· <b>Self-inflammability:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product is not explosive. Not determined.
· <b>Critical values for explosion:</b>	
· <b>Lower:</b>	Not determined.
· <b>Upper:</b>	Not determined.
· <b>Steam pressure:</b>	Not determined.
· <b>Density at 20 °C</b>	1.59-1.61 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>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
  - **Additional information:** -

### SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
  - **Acute toxicity** Based on available data, the classification criteria are not met.

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**· LD/LC50 values that are relevant for classification:**

**8042-47-5 White mineral oil, petroleum**

Oral	LD50	>5,000 mg/kg (rat) (OECD 401)
Dermal	LD50	>2,000 mg/kg (rabbit) (OECD 402)
Inhalative	LC0/4h	≥5 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:**

**8042-47-5 White mineral oil, petroleum**

LC50/96h >100 mg/l (fish)

· **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**

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.

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Non contaminated packagings can be used for recycling.

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**SECTION 14: Transport information**

- |  |                 |
|--|-----------------|
| · 14.1 UN-Number<br>· ADR, IMDG, IATA  | Void            |
| · 14.2 UN proper shipping name<br>· ADR, IMDG, IATA                          | Void            |
| · 14.3 Transport hazard class(es)<br>· ADR, ADN, IMDG, IATA<br>· Class       | Void            |
| · 14.4 Packing group<br>· ADR, IMDG, IATA                                    | Void            |
| · 14.5 Environmental hazards:<br>· Marine pollutant:                         | No              |
| · 14.6 Special precautions for user  | Not applicable. |
| · 14.7 Transport in bulk according to Annex II of<br>Marpol and the IBC Code | 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.
- 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**

H372 Causes damage to organs through prolonged or repeated exposure.

· **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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1