

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

· **1.1 Product identifier**

· **Trade name:** PANAVIA 21 ; CATALYST PASTE

· **Article number:** 050-PC

· **Registration number** Not applicable

· **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 materials

· **1.3 Details of the supplier of the safety data sheet**

· **Supplier :**

Kuraray Europe GmbH
Philipp-Reis-Str. 4,
65795 Hattersheim am Main
Germany

Phone: +49 (0)69 305 35 835

E-mail: dental.eu@kuraray.com

· **Further information obtainable from:** Supplier

· **1.4 Emergency telephone number:**

[United Kingdom] National Poisons Information Service (NPIS): +44 (0)344 892 0111 Only for NHS and other healthcare professionals

3E Company; (UK) 0 800 680 0425 (GB) +44 20 35147487 (AU) +61 2 80363166 *Kuraray Access Code: 334674

* **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 GB CLP regulation.

· **Additional information**

Medical devices as defined in Regulation (EU) 2017/745 and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (GB CLP/GHS) usually if they are in the finished state and intended for the final user.

· **2.2 Label elements**

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

· **Hazard pictograms** Void

· **Signal word** Void

· **Hazard statements** Void

· **Labelling of packages where the contents do not exceed 125 ml**

· **Precautionary statements**

EUH208: Contains benzoyl peroxide. May produce an allergic reaction.

EUH210: Safety data sheet available on request.

· **2.3 Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

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

· **3.2 Mixtures**

· **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 14808-60-7	Quartz (SiO ₂)	>80%
EINECS: 238-878-4	substance with a Community workplace exposure limit	
CAS: 94-36-0	benzoyl peroxide	<1%
EINECS: 202-327-6	Org. Perox. B, H241; Eye Irrit. 2, H319; Skin Sens. 1, H317	

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· Other ingredients:

Hydrophobic aromatic dimethacrylate
10-Methacryloyloxydecyl dihydrogen phosphate
Hydrophobic aliphatic dimethacrylate
Amorphous silica

· **Additional information:** Silicon oxide; Nanoform, Amorphous silica, particle size 1 - 100 nm

SECTION 4: First aid measures**· 4.1 Description of first aid measures**

- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist 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, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

· 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.

SECTION 6: Accidental release measures**· 6.1 Personal precautions, protective equipment and emergency procedures** See Section 8.**· 6.2 Environmental precautions:** No special measures required.**· 6.3 Methods and material for containment and cleaning up:**

Pick up mechanically. Ensure adequate ventilation.

· 6.4 Reference to other sections No dangerous substances are released.**SECTION 7: Handling and storage****· 7.1 Precautions for safe handling** No special measures required.**· Information about fire - and explosion protection:** No special measures required.**· 7.2 Conditions for safe storage, including any incompatibilities****· Storage:**

· **Requirements to be met by storerooms and receptacles:** Store in a refrigerator (2-8°C).

· **Information about storage in one common storage facility:** Not required.

· Further information about storage conditions:

Keep container tightly sealed.

Store in cool, dry conditions in well sealed receptacles.

Protect from heat and direct sunlight.

· 7.3 Specific end use(s) No further relevant information available.

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SECTION 8: Exposure controls/personal protection

· 8.1 Control parameters

· Ingredients with limit values that require monitoring at the workplace:

94-36-0 benzoyl peroxide

WEL (Great Britain) | Long-term value: 5 mg/m³14808-60-7 Quartz (SiO₂)BOELV (EU) | Long-term value: 0.1* mg/m³

*respirable fraction

· Additional information: The lists valid during the making were used as basis.

· 8.2 Exposure controls

· Appropriate engineering controls No further data; see section 7.

· Personal protective equipment:

· General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

· Respiratory protection: Suitable respiratory protective device recommended.

· Hand protection



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

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

· 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 trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye/face protection Safety glasses

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SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· Physical state	Solid
· Colour:	White
· Odour:	Odourless
· Melting point/freezing point:	Not determined
· Boiling point or initial boiling point and boiling range	Not determined
· Flammability	Not determined.
· Lower and upper explosion limit	Not determined
· Lower:	Not determined
· Upper:	Not determined
· Flash point:	Not determined
· Auto-ignition temperature:	Not determined
· Decomposition temperature:	Not determined

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· pH	Not determined
· Viscosity:	Not determined
· Solubility	
· water:	Insoluble.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not determined
· Density and/or relative density	
· Density:	2.0 g/cm ³
· Relative density	Not determined
· Relative vapour density	Not determined
· Particle characteristics	See section 3.
· 9.2 Other information	
· Important information on protection of health and environment, and on safety.	
· Explosive properties:	Product does not present an explosion hazard.
· Change in condition	
· Oxidising gases	Void
· 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**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used 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:** Carbon monoxide and carbon dioxide

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.
- **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** May cause an allergic skin reaction.
- **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.

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- **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:** 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.

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

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

- **12.6 Endocrine disrupting properties**

The product does not contain substances with endocrine disrupting properties.

- **12.7 Other adverse effects**

- **Additional ecological information:**

- **General notes:** Not hazardous for water.

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SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**

- **Recommendation** Smaller quantities can be disposed of with household waste.

- **Uncleaned packaging:**

- **Recommendation:**

Waste Framework Directive (Directive 2008/98/EC on waste)

O-ring used at the top of the plunger in the syringe contains 1% each of SVHC substances.

1. Octamethylcyclotetrasiloxane (D4) (CAS 556-67-2)

2. Decamethylcyclopentasiloxane (D5) (CAS 541-02-6)

3. Dodecamethylcyclohexasiloxane (D6) (CAS 540-97-6)

SCIP number: 28136f8a-3a55-41a6-8285-7cc3d0212efd

The SCIP number shall be communicated down to waste operators of the product.

For more information about the directive, visit ECHA website: <https://echa.europa.eu/understanding-wfd>

Disposal must be made in accordance with official regulations.

Disposal must be made according to official regulations.

SECTION 14: Transport information

- **14.1 UN number or ID number**

- **ADR, ADN, IMDG, IATA** Void

- **14.2 UN proper shipping name**

- **ADR, ADN, IMDG, IATA** Void

- **14.3 Transport hazard class(es)**

- **ADR, ADN, IMDG, IATA** Void

- **Class**

- **14.4 Packing group**

- **ADR, ADN, IMDG, IATA** Void

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· 14.5 Environmental hazards:	
· Marine pollutant:	No
· 14.6 Special precautions for user	
· 14.7 Maritime transport in bulk according to IMO instruments	
· UN "Model Regulation":	Void

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SECTION 15: Regulatory information**· 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

· Directive 94/33/EC: Care should be taken when people under 18 handle this product.

· Directive 94/85/EEC: No further relevant information available.

· Named dangerous substances - ANNEX I None of the ingredient is listed.

· Regulation (EU) No 649/2012

· 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.

· National regulations:**· Information about limitation of use:**

Waste Framework Directive (Directive 2008/98/EC on waste)

O-ring used at the top of the plunger in the syringe contains 1% each of SVHC substances.

1. Octamethylcyclotetrasiloxane (D4) (CAS 556-67-2)

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· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· Relevant phrases

H241 Heating may cause a fire or explosion.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

· Abbreviations and acronyms:

ELINCS: European List of Notified Chemical Substances

Org. Perox. B: Organic peroxides – Type B

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

· * Data compared to the previous version altered.