

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

1.1 Product identifier

- **Trade name:** PANAVIA F 2.0 ; PASTE B (TC, White, Light, Opaque)
- **Article number:** 089-PB
- **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 material

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

Acute Tox. 4 H302 Harmful if swallowed.
Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2 H319 Causes serious eye irritation.
Carc. 2 H351 Suspected of causing cancer. Route of exposure: Inhalation.

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

The product is classified and labelled according to the GB CLP regulation.

Hazard pictograms



GHS07 GHS08

- **Signal word** Warning

Hazard-determining components of labelling:

sodium fluoride
titanium dioxide

Hazard statements

H302 Harmful if swallowed.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H351 Suspected of causing cancer. Route of exposure: Inhalation.

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· **Precautionary statements**

- P280 Wear protective gloves / eye protection / face protection.
 P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
 P330 Rinse mouth.
 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P308+P313 IF exposed or concerned: Get medical advice/attention.
 P321 Specific treatment (see on this label).
 P332+P313 If skin irritation occurs: Get medical advice/attention.
 P337+P313 If eye irritation persists: Get medical advice/attention.
 P405 Store locked up.
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

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

· **Precautionary statements**

- EUH032: Contact with acids liberates very toxic gas.
 EUH212: Warning! Hazardous respirable dust may be formed when used. Do not breathe dust.

· **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: 7681-49-4	sodium fluoride	≤10%
EINECS: 231-667-8	☠ Acute Tox. 3, H301; ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319, EUH032	
CAS: 13463-67-7	titanium dioxide	<10%
EINECS: 236-675-5	☠ Carc. 2, H351	

· **Other ingredients:**

- Silanated barium glass filler
 Hydrophobic aromatic dimethacrylate
 Hydrophobic aliphatic dimethacrylate
 Hydrophilic aliphatic dimethacrylate
 Catalyst
 Accelerators
 Pigment

SECTION 4: First aid measures

· **4.1 Description of first aid measures**

· **General information:**

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

- **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:** Call for a doctor immediately.

· **4.2 Most important symptoms and effects, both acute and delayed**

No further relevant information available.

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- **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:**
Mouth respiratory protective device.
Wear fully protective suit.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** See Section 8.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Dispose contaminated material as waste according to section 13.
- **6.4 Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** Prevent formation of dust.
- **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:**
Do not store together with acids.
Store away from oxidising agents.
Store away from reducing agents.
- **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.

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**

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

7681-49-4 sodium fluoride

WEL	Long-term value: 2.5 mg/m ³ as F
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13463-67-7 titanium dioxide

WEL	Long-term value: 10* 4** mg/m ³ *total inhalable **respirable
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- **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:**
 Keep away from foodstuffs, beverages and feed.
 Immediately remove all soiled and contaminated clothing
 Wash hands before breaks and at the end of work.
 Avoid contact with the skin.
 Avoid contact with the eyes.
- **Respiratory protection:**
 In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
- **Hand protection**



Protective gloves

Neoprene 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**



Tightly sealed goggles

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **Physical state** Solid
- **Colour:** Colored
- **Odour:** Odourless
- **Melting point/freezing point:** 1012 °C (sodium fluoride)
- **Boiling point or initial boiling point and boiling range** 1704 °C (sodium fluoride)
- **Flammability** Not determined
- **Lower and upper explosion limit**
- **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.
· Kinematic 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	Not determined.

· 9.2 Other information	No further relevant information available.
· Important information on protection of health and environment, and on safety.	Not determined
· Explosive properties:	Product does not present an explosion hazard.
· Solvent separation test:	Not determined
· Water:	Not determined
· VOC (EC)	Not determined
· Change in condition	
· Softening point/range	
· Oxidising properties	Not determined
· 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 Harmful if inhaled.

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

7681-49-4 sodium fluoride

Oral	LD50	44 mg/kg (mouse)
		52 mg/kg (rat)

13463-67-7 titanium dioxide

Oral	LD50	>20,000 mg/kg (rat)
Dermal	LD50	>10,000 mg/kg (rabbit)
Inhalative	LC50/4 h	>6.82 mg/l (rat)

- **Skin corrosion/irritation** Causes skin irritation.
- **Serious eye damage/irritation** Causes serious eye irritation.
- **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** Suspected of causing cancer. Route of exposure: Inhalation.
- **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:** 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:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

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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 · Class	Void
· 14.4 Packing group · ADR, ADN, 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.
· UN "Model Regulation":	Void

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.

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

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

- H301 Toxic if swallowed.
- H315 Causes skin irritation.
- H319 Causes serious eye irritation.
- H351 Suspected of causing cancer.
- EUH032 Contact with acids liberates very toxic gas.

· Abbreviations and acronyms:

- ELINCS: European List of Notified Chemical Substances
- VOC: Volatile Organic Compounds (USA, EU)
- Acute Tox. 3: Acute toxicity – Category 3
- Acute Tox. 4: Acute toxicity – Category 4
- Skin Irrit. 2: Skin corrosion/irritation – Category 2
- Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
- Carc. 2: Carcinogenicity – Category 2

- * Data compared to the previous version altered.