

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

Printing date 11.09.2023

Version number 7

Revision date: 06.09.2023

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.

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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 through 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.