

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

1.1 Product identifier

Trade name: PANAVIA F 2.0 ; PASTE B

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 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:

[Malta] National poisons helpline; 1774 to the public from Monday to Sunday between 8:00 and 20:00

[3E Company] (Great Britain)+44 20 35147487 (United Kingdom)800 680 0425 (UK English)+44 8 08 189 0979 (Europe Non-Specific)+1 760 476 3962 *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.

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 (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 CLP regulation.

Hazard pictograms



GHS07

Signal word Warning

Hazard-determining components of labelling:

sodium fluoride

Hazard statements

H302 Harmful if swallowed.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

Precautionary statements

P264 Wash thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P280 Wear protective gloves / eye protection / face protection.

P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

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- 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.
 P332+P313 If skin irritation occurs: Get medical advice/attention.
 P362+P364 Take off contaminated clothing and wash it before reuse.
 P337+P313 If eye irritation persists: Get medical advice/attention.
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Additional Information

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	5-13%
EINECS: 231-667-8	☠ Acute Tox. 3, H301; ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319, EUH032	

SECTION 4: First aid measures

4.1 Description of first aid measures

General information:

Immediately remove any clothing soiled by the product.

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

• **After inhalation:** In case of unconsciousness place patient stably in side position for transportation.

• **After skin contact:** Immediately wash with water and soap and rinse thoroughly.

After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

• **After swallowing:** Call for a doctor immediately.

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.

Use fire extinguishing methods suitable to surrounding conditions.

• **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.

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- **6.2 Environmental precautions:** Do not allow product to reach sewage system or any water course.
- **6.3 Methods and material for containment and cleaning up:**
 Dispose contaminated material as waste according to section 13.
 Contain spill, then place in a suitable container. Minimize dust generation. Do not flush to sewer or allow to enter waterways.
 Vacuum or sweep material and place in a disposal container. Provide ventilation.
 Use appropriate Personal Protective Equipment (PPE).
- **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**
 Avoid contact with skin and eyes. Do not swallow. Avoid generating dust. Do not breathe dust/fume/gas/mist/vapors/spray.
- **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.

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

IOELV (EU)	Long-term value: 2.5 mg/m ³ as F
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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 eyes and skin.
- **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.

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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
· General Information

· Physical state	Solid
· Colour:	Colored
· 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	
· Lower:	Not applicable.
· Upper:	Not applicable.
· Flash point:	Not applicable
· Auto-ignition temperature:	Not applicable.
· Decomposition temperature:	Not applicable.
· pH	Not determined.
· Kinematic viscosity	Not applicable.
· Solubility	
· water:	Insoluble.
· Partition coefficient n-octanol/water (log value)	Not applicable.
· Vapour pressure:	Not applicable.
· Density at 20 °C:	2 g/cm ³
· Relative vapour density	Not applicable.
· Particle characteristics	Not determined.

· 9.2 Other information
· Information with regard to physical hazard classes

· Explosives	Product does not present an explosion hazard.
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void

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Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31

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· 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** No hazardous reaction when handled and stored according to provisions.
- **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 swallowed.

· **LD/LC50 values relevant for classification:****7681-49-4 sodium fluoride**

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

- **Primary irritant effect:**
- **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** 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.
- **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.

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- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties** For information on endocrine disrupting properties see section 11.
- **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:**
Dispose of packaging according to regulations on the disposal of packagings.
Waste Framework Directive (Directive 2008/98/EC on waste)
[No. 089-PB] Syringe seal contains 0.1% or more each of SVHC.
1. Octamethylcyclotetrasiloxane (D4) (CAS 556-67-2)
2. Decamethylcyclopentasiloxane (D5) (CAS 541-02-6)
3. Dodecamethylcyclohexasiloxane (D6) (CAS 540-97-6)
SCIP number: c0f9fd30-49de-4e94-b79b-3fc9c3d03f75
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>

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: | Not applicable. |
| · 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.

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· **REGULATION (EU) 2019/1021 on persistent organic pollutants (POP)**

None of the ingredients is listed.

· **Regulation (EU) No 649/2012**

None of the ingredients is listed.

· **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.

· **REGULATION (EU) 2024/590 on substances that deplete the ozone layer**

None of the ingredients is listed.

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

[No. 089-PB] Syringe seal contains 0.1% or more each of SVHC.

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

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

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

SCIP number: c0f9fd30-49de-4e94-b79b-3fc9c3d03f75

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>

· **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.

This Safety Data Sheet is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2020/878.

· **Relevant phrases**

H301 Toxic if swallowed.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

EUH032 Contact with acids liberates very toxic gas.

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

The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No 1272/2008.

· **Abbreviations and acronyms:**

ELINCS: European List of Notified Chemical Substances

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

· *** Data compared to the previous version altered.**

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