

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

Printing date 08.03.2023



Version number 7

Revision date: 08.03.2023

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

- **1.1 Product identifier**
- **Trade name:** ALLOY PRIMER
- **Article number:** 054
- **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** Adhesive, dental metal
- **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:**  
( UK ) 0 800 680 0425  
( GB ) +44 20 35147487  
( AU ) +61 2 80363166  
\* 3E Company  
\* Kuraray Access Code:334674

**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
Flam. Liq. 2 H225 Highly flammable liquid and vapour.  
Eye Irrit. 2 H319 Causes serious eye irritation.  
STOT SE 3 H336 May cause drowsiness or dizziness.
- **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**  
  
GHS02 GHS07
- **Signal word** Danger
- **Hazard-determining components of labelling:**  
acetone
- **Hazard statements**  
H225 Highly flammable liquid and vapour.  
H319 Causes serious eye irritation.  
H336 May cause drowsiness or dizziness.
- **Precautionary statements**  
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  
P240 Ground and bond container and receiving equipment.

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- P241 Use explosion-proof [electrical/ventilating/lighting] equipment.  
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.  
P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.  
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].  
P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
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** EUH066: Repeated exposure may cause skin dryness or cracking
- **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: 67-64-1	acetone	>90%
EINECS: 200-662-2	⚠ Flam. Liq. 2, H225; ⚠ Eye Irrit. 2, H319; STOT SE 3, H336, EUH066	

- **Other ingredients:**  
6-(4-Vinylbenzyl-N-propyl)amino-1,3,5-triazine-2,4-dithione  
10-Methacryloyloxydecyl dihydrogen phosphate

**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. If symptoms persist, consult a doctor.
- **After swallowing:**  
Do not induce vomiting; call for medical help immediately.  
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:**  
CO<sub>2</sub>, 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:**  
Wear self-contained respiratory protective device.

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Wear fully protective suit.

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**SECTION 6: Accidental release measures**

- **6.1 Personal precautions, protective equipment and emergency procedures** See Section 8.
- **6.2 Environmental precautions:**
  - Dilute with plenty of water.
  - Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
  - Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
  - Ensure adequate ventilation.
- **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**
  - Ensure good ventilation/exhaustion at the workplace.
  - Prevent formation of aerosols.
- **Information about fire - and explosion protection:**
  - Keep ignition sources away - Do not smoke.
  - Protect against electrostatic charges.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store in a cool location (2-25°C).
- **Information about storage in one common storage facility:**
  - 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:****67-64-1 acetone**

WEL	Short-term value: 3620 mg/m <sup>3</sup> , 1500 ppm
	Long-term value: 1210 mg/m <sup>3</sup> , 500 ppm

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

· **8.2 Exposure controls**

- **Appropriate engineering controls** No further data; see item 7.

· **Personal protective equipment:**· **General protective and hygienic measures:**

- Immediately remove all soiled and contaminated clothing
- Wash hands before breaks and at the end of work.
- Avoid contact with the eyes.

- **Respiratory protection:** Use suitable respiratory protective device in case of insufficient ventilation.

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**· Hand protection**

Solvent resistant gloves

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

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

**· Material of gloves** Butyl rubber, BR**· 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**

Liquid

**· Colour:**

Transparent

**· Odour:**

Acetone-like

**· Melting point/freezing point:**

-94.7 °C (acetone)

**· Boiling point or initial boiling point and boiling range**

55 °C (acetone)

**· Flammability**

Flammable.

**· Lower and upper explosion limit****· Lower:**

2.6 Vol % (acetone)

**· Upper:**

13.0 Vol % (acetone)

**· Flash point:**

-19 °C (acetone)

**· Auto-ignition temperature:**

465.0 °C (acetone)

**· Decomposition temperature:**

Not determined

**· pH**

Not determined

**· Viscosity:**

Not determined

**· Kinematic viscosity**

Not determined.

**· Solubility****· water:**

Partly miscible.

**· Partition coefficient n-octanol/water (log value)**

-0.24 (acetone)

**· Vapour pressure:**

233.0 hPa (20°C, acetone)

**· Density and/or relative density****· Density:**0.79 g/cm<sup>3</sup> (acetone)**· Relative density**

Not determined

**· Relative vapour density**2.0 g/cm<sup>3</sup> (acetone, air=1)**· 9.2 Other information****· Appearance:****· Form:**

Liquid

**· Important information on protection of health and environment, and on safety.****· Explosive properties:**

Product is not explosive. However, formation of explosive air/vapour mixtures are possible.

**· Change in condition****· Softening point/range****· Oxidising properties**

Not determined

**· Evaporation rate**

Not determined

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· <b>Oxidising gases</b>	Void
· <b>Gases under pressure</b>	Void
· <b>Flammable liquids</b>	
Highly flammable liquid and vapour.	
· <b>Flammable solids</b>	Void
· <b>Self-reactive substances and mixtures</b>	Void
· <b>Pyrophoric liquids</b>	Void
· <b>Pyrophoric solids</b>	Void
· <b>Self-heating substances and mixtures</b>	Void
· <b>Substances and mixtures, which emit flammable gases in contact with water</b>	Void
· <b>Oxidising liquids</b>	Void
· <b>Oxidising solids</b>	Void
· <b>Organic peroxides</b>	Void
· <b>Corrosive to metals</b>	Void
· <b>Desensitised explosives</b>	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.

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

#### 67-64-1 acetone

Oral	LD50	5800 mg/kg (rat)
Dermal	LD50	20000 mg/kg (rabbit)

- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **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**  
May cause drowsiness or dizziness.
- **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.

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### 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** 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:** Disposal must be made according to official regulations.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

### SECTION 14: Transport information

- |   |                             |
|---|-----------------------------|
| · <b>14.1 UN number or ID number</b>  |                             |
| · <b>ADR, IMDG, IATA</b>  | 1090                        |
| · <b>14.2 UN proper shipping name</b>   | 1090 ACETONE, solution      |
| · <b>14.3 Transport hazard class(es)</b>  |                             |
| · <b>ADR, IMDG, IATA</b>  |                             |
|  |                             |
| · <b>Class</b>  | 3 Flammable liquids.        |
| · <b>Label</b>  | 3                           |
| · <b>14.4 Packing group</b>   |                             |
| · <b>ADR, IMDG, IATA</b>  | II                          |
| · <b>14.5 Environmental hazards:</b>  |                             |
| · <b>Marine pollutant:</b>  | No                          |
| · <b>14.6 Special precautions for user</b>  | Warning: Flammable liquids. |
| · <b>Hazard identification number (Kemler code):</b>                                | 33                          |
| · <b>EMS Number:</b>  | F-E,S-D                     |
| · <b>14.7 Maritime transport in bulk according to IMO instruments</b>               | Not applicable.             |

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## · Transport/Additional information:

### · ADR

· Limited quantities (LQ)

LQ4

· Transport category

2

· Tunnel restriction code

D/E

· UN "Model Regulation":

UN1090; ACETONE, solution; 3; II

## 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.

#### · Chemical safety assessment

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

· Seveso category FLAMMABLE LIQUIDS

· Qualifying quantity (tonnes) for the application of lower-tier requirements 5,000 t

· Qualifying quantity (tonnes) for the application of upper-tier requirements 50,000 t

· Regulation (EU) No 649/2012

#### · Regulation (EC) No 273/2004 on drug precursors

67-64-1 acetone

3

#### · Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

67-64-1 acetone

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· 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

H225 Highly flammable liquid and vapour.

H319 Causes serious eye irritation.

H336 May cause drowsiness or dizziness.

EUH066 Repeated exposure may cause skin dryness or cracking.

### · Abbreviations and acronyms:

ELINCS: European List of Notified Chemical Substances

Flam. Liq. 2: Flammable liquids – Category 2

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

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

· \* Data compared to the previous version altered.

GB



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

- **1.1 Product identifier**
- **Trade name:** PANAVIA F 2.0 ; PASTE A
- **Article number:** 089-PA
- **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] Only for NHS and other healthcare professionals; UK National Poisons Information Service (NPIS): +44 (0)344 892 0111 Ireland NPIC: +353 (0)1 809 2566  
For members of Public; NHS 111 in England: 111, NHS 24 in Scotland: 111, NHS Direct in Wales: 111 or 0845 4647, Ireland NPIC: +353 (0)1 809 2166(8 am to 10 pm)  
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
- **Additional Information**  
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 <sub>2</sub> )	> 70%
EINECS: 238-878-4	substance with a Community workplace exposure limit	

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**Trade name: PANA VIA F 2.0 ; PASTE A**




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CAS: 94-36-0

benzoyl peroxide

&lt; 1%

EINECS: 202-327-6


 Org. Perox. B, H241;  Eye Irrit. 2, H319; Skin Sens. 1, H317

· **Other ingredients:**

Hydrophobic aromatic dimethacrylate  
Hydrophobic aliphatic dimethacrylate  
10-Methacryloyloxydecyl dihydrogen phosphate  
Silanated amorphous silica  
Hydrophilic aliphatic dimethacrylate  
dl-Camphorquinone  
Initiator

· **Additional information:** Silicon oxide; Nanoform, Silanated 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:**

CO<sub>2</sub>, 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.

· **6.2 Environmental precautions:** No special measures required.

· **6.3 Methods and material for containment and cleaning up:**

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.

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**Trade name: PANA VIA F 2.0 ; PASTE A**

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- **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.
  - Protect from heat and direct sunlight.
  - Store in cool, dry conditions in well sealed receptacles.
- **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:**

##### **14808-60-7 Quartz (SiO<sub>2</sub>)**

BOELV (EU)	Long-term value: 0.1 * mg/m <sup>3</sup> *respirable fraction
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##### **94-36-0 benzoyl peroxide**

WEL (Great Britain)	Long-term value: 5 mg/m <sup>3</sup>
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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:** Wash hands before breaks and at the end of work.
- **Respiratory protection:** Suitable respiratory protective device recommended.
- **Hand protection**

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

## SECTION 9: Physical and chemical properties

### · 9.1 Information on basic physical and chemical properties

#### · **General Information**

- |   |                 |
|---|-----------------|
| · <b>Physical state</b>   | Solid           |
| · <b>Colour:</b>  | Colored         |
| · <b>Odour:</b>   | Odourless       |
| · <b>Melting point/freezing point:</b>                            | Not determined. |
| · <b>Boiling point or initial boiling point and boiling range</b> | Not determined. |

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Trade name: PANA VIA F 2.0 ; PASTE A

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· 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:	2.2 g/cm <sup>3</sup>
· Relative vapour density	Not applicable.
· Particle characteristics	See Section 3.

## · 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
· 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.

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

## 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-PA] 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: 848c0afa-df9c-4f20-9f87-ac3d3ac24c9b  
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

(Contd. on page 6)

GB

## Safety data sheet

### according to 1907/2006/EC, Article 31

Printing date 08.07.2024

Version number 7 (replaces version 6)

Revision date: 28.06.2024

Trade name: PANA VIA F 2.0 ; PASTE A

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- |   |                 |
|---|-----------------|
| · <b>14.3 Transport hazard class(es)</b>                              |                 |
| · <b>ADR, IMDG, IATA</b>  |                 |
| · <b>Class</b>  | Void            |
| · <b>14.4 Packing group</b>   |                 |
| · <b>ADR, ADN, IMDG, IATA</b>   | Void            |
| · <b>14.5 Environmental hazards:</b>                                  | Not applicable. |
| · <b>14.6 Special precautions for user</b>                            | Not applicable. |
| · <b>14.7 Maritime transport in bulk according to IMO instruments</b> | Not applicable. |
| · <b>UN "Model Regulation":</b>                                       | Void            |

## SECTION 15: Regulatory information

### · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

#### · **Regulated explosives precursors**

None of the ingredients is listed.

#### · **Regulated poisons**

None of the ingredients is listed.

#### · **Reportable explosives precursors**

None of the ingredients is listed.

#### · **Reportable poisons**

None of the ingredients is listed.

· **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**

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 (EC) No 1005/2009 on substances that deplete the ozone layer – ANNEX I (Ozone-depleting potential)**

None of the ingredients is listed.

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

[No. 089-PA] 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: 848c0afa-df9c-4f20-9f87-ac3d3ac24c9b

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.

GB

(Contd. on page 7)

**Trade name: PANA VIA F 2.0 ; PASTE A**

(Contd. of page 6)

**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**

H241 Heating may cause a fire or explosion.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

**· 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

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.**

GB

## 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:**  
[United Kingdom] Only for NHS and other healthcare professionals; UK National Poisons Information Service (NPIS): +44 (0)344 892 0111 Ireland NPIC: +353 (0)1 809 2566  
For members of Public; NHS 111 in England: 111, NHS 24 in Scotland: 111, NHS Direct in Wales: 111 or 0845 4647, Ireland NPIC: +353 (0)1 809 2166(8 am to 10 pm)  
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.
- **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
- **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.

(Contd. on page 2)



**Trade name: PANA VIA F 2.0 ; PASTE B**

(Contd. of page 1)

- P280 Wear 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.  
 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**

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	< 15%
EINECS: 231-667-8	☠ Acute Tox. 3, H301; ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319, EUH032	

**Other ingredients:**

Silanated barium glass filler  
 Hydrophobic aromatic dimethacrylate  
 Hydrophobic aliphatic dimethacrylate  
 Hydrophilic aliphatic dimethacrylate  
 Catalyst  
 Accelerators  
 Pigments

**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.

GB

(Contd. on page 3)

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

Printing date 28.06.2024

Version number 8 (replaces version 7)

Revision date: 28.06.2024

**Trade name: PANA VIA F 2.0 ; PASTE B**

(Contd. of page 2)

**SECTION 5: Firefighting measures**

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, 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:** Mouth respiratory protective device.

**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.  
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:** Do not store together with acids.
- **Further information about storage conditions:**  
Keep container tightly sealed.  
Protect from heat and direct sunlight.  
Store in cool, dry conditions in well sealed receptacles.
- **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 (Great Britain)	Long-term value: 2.5 mg/m <sup>3</sup> as F
IOELV (EU)	Long-term value: 2.5 mg/m <sup>3</sup> as F

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GB

Trade name: PANA VIA F 2.0 ; PASTE B

(Contd. of page 3)

**13463-67-7 titanium dioxide**

WEL (Great Britain)	Long-term value: 10* 4** mg/m <sup>3</sup> *total inhalable **respirable
---------------------	---

· **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.

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**

1,704 °C (7681-49-4 sodium fluoride)

· **Flammability**

Not determined.

· **Lower and upper explosion limit**

· **Lower:**

Not applicable.

· **Upper:**

Not applicable.

· **Flash point:**

Not applicable

· **Auto-ignition temperature:**

Not applicable.

(Contd. on page 5)

Trade name: PANA VIA F 2.0 ; PASTE B

(Contd. of page 4)

· <b>Decomposition temperature:</b>	Not applicable.
· <b>pH</b>	Not determined.
· <b>Kinematic viscosity</b>	Not applicable.
· <b>Solubility</b>	
· <b>water:</b>	Insoluble.
· <b>Partition coefficient n-octanol/water (log value)</b>	Not applicable.
· <b>Vapour pressure:</b>	Not applicable.
· <b>Density at 20 °C:</b>	2 g/cm <sup>3</sup>
· <b>Relative vapour density</b>	Not applicable.
· <b>Particle characteristics</b>	Not determined.

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

· <b>Explosives</b>	Product does not present an explosion hazard.
· <b>Flammable gases</b>	Void
· <b>Aerosols</b>	Void
· <b>Oxidising gases</b>	Void
· <b>Gases under pressure</b>	Void
· <b>Flammable liquids</b>	Void
· <b>Flammable solids</b>	Void
· <b>Self-reactive substances and mixtures</b>	Void
· <b>Pyrophoric liquids</b>	Void
· <b>Pyrophoric solids</b>	Void
· <b>Self-heating substances and mixtures</b>	Void
· <b>Substances and mixtures, which emit flammable gases in contact with water</b>	Void
· <b>Oxidising liquids</b>	Void
· <b>Oxidising solids</b>	Void
· <b>Organic peroxides</b>	Void
· <b>Corrosive to metals</b>	Void
· <b>Desensitised explosives</b>	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 swallowed.

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

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

- **Skin corrosion/irritation**  
Causes skin irritation.

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GB

## Safety data sheet

### according to 1907/2006/EC, Article 31

Printing date 28.06.2024

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Trade name: PANA VIA F 2.0 ; PASTE B

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- **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**

· <b>Endocrine disrupting properties</b>
--

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** 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

- |                                      |      |
|--------------------------------------|------|
| · <b>14.1 UN number or ID number</b> | Void |
| · <b>ADR, ADN, IMDG, IATA</b>        |      |

(Contd. on page 7)

GB

# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 28.06.2024

Version number 8 (replaces version 7)

Revision date: 28.06.2024

Trade name: PANA VIA F 2.0 ; PASTE B

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- |  |                 |
|--|-----------------|
| · 14.2 UN proper shipping name                                 |                 |
| · ADR, ADN, IMDG, IATA   | Void            |
| · 14.3 Transport hazard class(es)                              |                 |
| · ADR, 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

#### · Regulated explosives precursors

None of the ingredients is listed.

#### · Regulated poisons

None of the ingredients is listed.

#### · Reportable explosives precursors

None of the ingredients is listed.

#### · Reportable poisons

7681-49-4 sodium fluoride

Listed

- 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

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 (EC) No 1005/2009 on substances that deplete the ozone layer – ANNEX I (Ozone-depleting potential)

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>

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GB

## Safety data sheet

### according to 1907/2006/EC, Article 31

Printing date 28.06.2024

Version number 8 (replaces version 7)

Revision date: 28.06.2024

**Trade name: PANA VIA F 2.0 ; PASTE B**

(Contd. of page 7)

· **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.**

GB



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

Printing date 02.09.2016

Version number 6

Revision: 02.09.2016

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier****Trade name:** PANAVIA F 2.0 ; ED PRIMER II Liquid A**Article number:** 070-A**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 for tooth surface conditioning**1.3 Details of the supplier of the safety data sheet****Manufacturer:**

Kuraray Europe GmbH  
Philipp-Reis-Str. 4,  
65795 Hattersheim am Main  
Germany  
Phone: +49 (0)69 305 35 840  
Fax: +49 (0)69 305 35 640  
E-mail: dental@kuraray.de

**Supplier:**

J & S Davis  
5 Whitworth Road, Stevenage,  
Hertfordshire, SG1 4QS  
Great Britain  
Tel: +44- (0) 1438 747344  
Fax: +44- (0)1438 758909  
E-mail: jsdsales@js-davis.co.uk

**Further information obtainable from:** Manufacturer or Supplier**1.4 Emergency telephone number:**

National Poisons information Service (London Centre)  
Guy's & St. Thomas' Hospital Trust  
Medical Toxicology Unit  
Avonley Road  
LONDON  
SE14 5ER  
Emergency telephone: (local) 0870 600 6266 or +44 20 7771 5394  
Administrative telephone: +44 20 7 771 53 10  
Facsimile number: +44 20 7 771 53 09

**SECTION 2: Hazards identification****2.1 Classification of the substance or mixture****Classification according to Regulation (EC) No 1272/2008**

GHS07

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction.

**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:**

2-hydroxyethyl methacrylate

(Contd. on page 2)

GB

# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 02.09.2016

Version number 6

Revision: 02.09.2016

**Trade name: PANA VIA F 2.0 ; ED PRIMER II Liquid A**

(Contd. of page 1)

**· Hazard statements**

- H315 Causes skin irritation.
- H319 Causes serious eye irritation.
- H317 May cause an allergic skin reaction.

**· Precautionary statements**

- P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
- P280 Wear protective gloves/protective clothing/eye protection/face protection.
- P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P321 Specific treatment (see on this label).
- P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
- P337+P313 If eye irritation persists: Get medical advice/attention.
- P302+P352 IF ON SKIN: Wash with plenty of water.
- P362+P364 Take off contaminated clothing and wash it before reuse.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

**· 2.3 Other hazards****· Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

## SECTION 3: Composition/information on ingredients

**· 3.1 Chemical characterisation: Substances** None**· 3.2 Chemical characterisation: Mixtures**

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

**· Dangerous components:**

CAS: 868-77-9	2-hydroxyethyl methacrylate	30-50%
EINECS: 212-782-2	⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	

**· Other ingredients:**

- 10-Methacryloyloxydecyl dihydrogen phosphate
- N-Methacryloyl-5-aminosalicylic acid
- Water
- Accelerators

## SECTION 4: First aid measures

**· 4.1 Description of first aid measures****· After inhalation:**

- Supply fresh air and to be sure call for a doctor.
- 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:**

- Do not induce vomiting; call for medical help immediately.
- 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.

GB

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

Printing date 02.09.2016

Version number 6

Revision: 02.09.2016

**Trade name: PANA VIA F 2.0 ; ED PRIMER II Liquid A**

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**SECTION 5: Firefighting measures**

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, 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:**  
Wear self-contained respiratory protective device.  
Wear fully protective suit.

**SECTION 6: Accidental release measures**

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Wear protective equipment. Keep unprotected persons away.
- **6.2 Environmental precautions:**  
Dilute with plenty of water.  
Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).  
Ensure adequate ventilation.
- **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**  
Ensure good ventilation/exhaustion at the workplace.  
Prevent formation of aerosols.
- **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:**  
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**

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 Control parameters**
- **Ingredients with limit 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.
- **Additional information:** The lists valid during the making were used as basis.

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# Safety data sheet

## according to 1907/2006/EC, Article 31

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Revision: 02.09.2016

Trade name: PANA VIA F 2.0 ; ED PRIMER II Liquid A

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- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
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:**  
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.
- **Protection of hands:**



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 through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:**



Tightly sealed goggles

## SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Liquid
Colour:	Transparent
Odour:	Odourless
- **pH-value:** Not determined
- **Change in condition**

Melting point/Melting range:	-12 °C (2-hydroxyethyl methacrylate)
Boiling point/Boiling range:	205 °C (2-hydroxyethyl methacrylate)
- **Flash point:** 97 °C (2-hydroxyethyl methacrylate)
- **Ignition temperature:** Not determined
- **Decomposition temperature:** Not determined
- **Danger of explosion:** Product does not present an explosion hazard.

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Trade name: PANA VIA F 2.0 ; ED PRIMER II Liquid A

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- **Explosion limits:**
  - Lower: Not determined
  - Upper: Not determined
- **Oxidising properties** Not determined
- **Vapour pressure:** Not determined
- **Density:** 1.1 g/cm<sup>3</sup>
- **Relative density** Not determined
- **Vapour density** Not determined
- **Evaporation rate** Not determined
- **Solubility in / Miscibility with water:** Partly miscible.
- **Partition coefficient (n-octanol/water):** Not determined
- **Viscosity:** Not determined
- **9.2 Other information** No further relevant information available.

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

### LD/LC50 values relevant for classification:

#### 868-77-9 2-hydroxyethyl methacrylate

Oral	LD50	4680 mg/kg (guinea pig)
		3275 mg/kg (mouse)
		5050 mg/kg (rat)

- **Primary irritant effect:**
- **Skin corrosion/irritation**  
Causes skin irritation.
- **Serious eye damage/irritation**  
Causes serious eye irritation.
- **Respiratory or skin sensitisation**  
May cause an allergic skin reaction.
- **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** Based on available data, the classification criteria are not met.

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Trade name: PANA VIA F 2.0 ; ED PRIMER II Liquid A

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· **Aspiration hazard** Based on available data, the classification criteria are not met.

### 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.
- **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.
- **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 together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

### SECTION 14: Transport information

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

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

Printing date 02.09.2016

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Revision: 02.09.2016

**Trade name: PANA VIA F 2.0 ; ED PRIMER II Liquid A**

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**SECTION 15: Regulatory information**

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
- **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**

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

**· Abbreviations and acronyms:**

Skin Irrit. 2: Skin corrosion/irritation – Category 2

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

Skin Sens. 1: Skin sensitisation – Category 1

- **\* Data compared to the previous version altered.**

GB



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

Printing date 01.08.2020

Version number 7

Revision: 01.08.2020

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

- **1.1 Product identifier**
- **Trade name:** PANAVIA F 2.0 ; ED PRIMER II Liquid B
- **Article number:** 070-B
- **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 for tooth surface conditioning
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer:**  
Kuraray Europe GmbH  
Philipp-Reis-Str. 4  
65795 Hattersheim am Main  
Germany  
Phone: +49 (0) 69 305 35835  
Fax: +49 (0) 69 305 9835835  
E-mail: dental.eu@kuraray.com
- **Further information obtainable from:** Manufacturer
- **1.4 Emergency telephone number:**  
  
(UK) 0 800 680 0425  
(GB) +44 20 35147487  
(AU) +61 2 80363166  
\* Verisk 3E  
\* 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 CLP regulation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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

Printing date 01.08.2020

Version number 7

Revision: 01.08.2020

**Trade name: PANA VIA F 2.0 ; ED PRIMER II Liquid B**

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**SECTION 3: Composition/information on ingredients****· 3.2 Chemical characterisation: Mixtures****· Description:** Mixture of substances listed below with nonhazardous additions.**· Dangerous components:** Void**· Other ingredients:**

N-Methacryloyl-5-aminosalicylic acid

Water

Catalysts

Accelerators

**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:**CO<sub>2</sub>, 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:** Dilute with plenty of water.**· 6.3 Methods and material for containment and cleaning up:**

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

**· 6.4 Reference to other sections** No dangerous substances are released.**SECTION 7: Handling and storage****· 7.1 Precautions for safe handling**

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

**· 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.

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## Safety data sheet

### according to 1907/2006/EC, Article 31

Printing date 01.08.2020

Version number 7

Revision: 01.08.2020

**Trade name: PANA VIA F 2.0 ; ED PRIMER II Liquid B**

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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

· **Additional information about design of technical facilities:** No further data; see item 7.· **8.1 Control parameters**· **Ingredients with limit 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.

· **Additional information:** The lists valid during the making were used as basis.· **8.2 Exposure controls**· **Personal protective equipment:**· **General protective and hygienic measures:**

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

· **Respiratory protection:** Not required.· **Protection of hands:**

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 protection:** Goggles recommended during refilling

### SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**· **General Information**· **Appearance:**

<b>Form:</b>	Liquid
<b>Colour:</b>	Transparent
<b>Odour:</b>	Odourless

· **pH-value:** Not determined· **Change in condition**

<b>Melting point/Melting range:</b>	Not determined
<b>Boiling point/Boiling range:</b>	Not determined

· **Flash point:** Not determined· **Ignition temperature:** Not determined· **Decomposition temperature:** Not determined· **Danger of explosion:** Product does not present an explosion hazard.

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## Safety data sheet

### according to 1907/2006/EC, Article 31

Printing date 01.08.2020

Version number 7

Revision: 01.08.2020

Trade name: PANA VIA F 2.0 ; ED PRIMER II Liquid B

(Contd. of page 3)

· <b>Explosion limits:</b>	
Lower:	Not determined
Upper:	Not determined
· <b>Oxidising properties</b>	Not determined
· <b>Vapour pressure:</b>	Not determined
· <b>Density:</b>	1.0 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 water:</b>	Fully miscible.
· <b>Partition coefficient (n-octanol/water):</b>	Not determined
· <b>Viscosity:</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**
- **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 toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **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.
- **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** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

### 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.
- **Additional ecological information:**
- **General notes:** Generally not hazardous for water

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

Printing date 01.08.2020

Version number 7

Revision: 01.08.2020

**Trade name: PANA VIA F 2.0 ; ED PRIMER II Liquid B**

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- **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** Smaller quantities can be disposed of with household waste.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

**SECTION 14: Transport information**

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

**SECTION 15: Regulatory information**

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**  
No further relevant information available.
- **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.

- **\* Data compared to the previous version altered.**

# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 24.02.2023

Version number 6

Revision date: 24.02.2023

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

- **1.1 Product identifier**
- **Trade name:** PANAVIA F 2.0 ; OXYGUARD II
- **Article number:** 089-O
- **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 for curing promotion and surface protection
- **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:**  
( UK ) 0 800 680 0425  
( GB ) +44 20 35147487  
( AU ) +61 2 80363166  
\* 3E Company  
\* 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** 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: 56-81-5 EINECS: 200-289-5	Glycerin	substance with a Community workplace exposure limit	50-70%
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· **Other ingredients:**

Polyethyleneglycol  
Catalyst

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

Printing date 24.02.2023

Version number 6

Revision date: 24.02.2023

**Trade name: PANA VIA F 2.0 ; OXYGUARD II**Accelerator  
Dye

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**SECTION 4: First aid measures**

- **4.1 Description of first aid measures**
- **General information:** No special measures required.
- **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:** 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.
- **6.2 Environmental precautions:**  
Dilute with plenty of water.  
Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **6.4 Reference to other sections**  
No dangerous substances are released.  
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** 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:**  
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.

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· 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:**

56-81-5 Glycerin

WEL Long-term value: 10 mg/m<sup>3</sup>· **Additional information:** The lists valid during the making were used as basis.

### · 8.2 Exposure controls

· **Appropriate engineering controls** No further data; see item 7.· **Personal protective equipment:**· **General protective and hygienic measures:**

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

· **Respiratory protection:** Not required.· **Hand protection**

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** Goggles recommended during refilling

## SECTION 9: Physical and chemical properties

### · 9.1 Information on basic physical and chemical properties

· **General Information**· **Physical state**

Liquid

· **Colour:**

Green

· **Odour:**

Odourless

· **Odour threshold:**

Not determined.

· **Melting point/freezing point:**

18.2 °C (glycerol)

· **Boiling point or initial boiling point and boiling range**

290.0 °C (glycerol)

· **Flammability**

Not determined.

· **Lower and upper explosion limit**· **Lower:**

0.9 Vol % (glycerol)

· **Upper:**

Not determined.

· **Flash point:**

160 °C (glycerol)

· **Auto-ignition temperature:**

400.0 °C (glycerol)

· **Decomposition temperature:**

Not determined

· **pH at 20 °C**

5.8~6.2

· **Viscosity:**

Not determined

· **Kinematic viscosity**

Not determined

· **Dynamic:**

Not determined

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· Solubility	
· water:	Fully miscible.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	0.1 hPa (20°C, glycerol)
· Density and/or relative density	
· Density:	Not determined.
· Relative density	Not determined
· Relative vapour density	Not determined.
· 9.2 Other information	
· Appearance:	
· Form:	Gel
· Important information on protection of health and environment, and on safety.	
· Explosive properties:	Product does not present an explosion hazard.
· Change in condition	
· Softening point/range	
· Oxidising properties	Not determined
· Evaporation rate	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 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 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.

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- **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**

· <b>Endocrine disrupting properties</b>
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None of the ingredients is listed.
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### 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** No further relevant information available.
- **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** Smaller quantities can be disposed of with household waste.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

### SECTION 14: Transport information

- |   |                 |
|---|-----------------|
| <ul style="list-style-type: none"> <li>· <b>14.1 UN number or ID number</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> </ul>                             | Void            |
| <ul style="list-style-type: none"> <li>· <b>14.2 UN proper shipping name</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> </ul>                            | Void            |
| <ul style="list-style-type: none"> <li>· <b>14.3 Transport hazard class(es)</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> <li>· <b>Class</b></li> </ul> | Void            |
| <ul style="list-style-type: none"> <li>· <b>14.4 Packing group</b></li> <li>· <b>ADR, IMDG, IATA</b></li> </ul>   | Void            |
| <ul style="list-style-type: none"> <li>· <b>14.5 Environmental hazards:</b></li> <li>· <b>Marine pollutant:</b></li> </ul>                                | No              |
| <ul style="list-style-type: none"> <li>· <b>14.6 Special precautions for user</b></li> </ul>  | Not applicable. |

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- |   |                 |
|---|-----------------|
| · <b>14.7 Maritime transport in bulk according to IMO instruments</b> | Not applicable. |
| · <b>UN "Model Regulation":</b>                                       | Void            |

\*

**SECTION 15: Regulatory information**

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**  
No further relevant information available.
- **Directive 94/33/EC:** Care should be taken when people under 18 handle this product.
- **Directive 94/85/EEC:** No further relevant information available.
- **Chemical safety assessment**
- **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.

- **Abbreviations and acronyms:** ELINCS: European List of Notified Chemical Substances
- **\* Data compared to the previous version altered.**

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