


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 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] (Great Britain (London))+44 20 351 47487, (United Kingdom - Domestic)+44 800 680 0425, (United Kingdom - International)+44 808 189 0979 (Europe Non-Specific)+1 760 476 3962 *Kuraray
Access Code: 334674

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
 - **Classification according to Regulation (EC) No 1272/2008**
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 GB CLP regulation.
 - **Hazard pictograms**
- 

GHS07
- **Signal word** Warning
 - **Hazard-determining components of labelling:**
2-hydroxyethyl methacrylate
 - **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.
P264 Wash thoroughly after handling.
P280 Wear protective gloves / eye protection / face protection.
P302+P352 IF ON SKIN: Wash with plenty of water.

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Trade name: PANAVIA F 2.0 ; ED PRIMER II Liquid A

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- P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P362+P364 Take off contaminated clothing and wash it before reuse.
- P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
- P321 Specific treatment (see on this label).
- P337+P313 If eye irritation persists: Get medical advice/attention.
- 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

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

Dangerous components:

CAS: 868-77-9	2-hydroxyethyl methacrylate	30-60%
EINECS: 212-782-2	⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** Immediately remove any clothing soiled by the product.
- **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:** If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed**
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
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:**
Before cleaning, pre-clean the equipment under running water with a damp cloth.
Avoid disposing of uncured product residues into the sewage system.

(Contd. on page 3)

Trade name: PANAVIA F 2.0 ; ED PRIMER II Liquid A

(Contd. of page 2)

- **6.3 Methods and material for containment and cleaning up:**
Dispose contaminated material as waste according to section 13.
Ensure adequate ventilation.
Absorb liquid components with liquid-binding material.
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**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
Avoid contact with skin and eyes. Do not swallow. Avoid generating dust. Do not breathe dust/fume/gas/mist/vapors/spray.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store in a refrigerator (2-8°C).
- **Information about storage in one common storage facility:** Not required
- **Further information about storage conditions:**
Keep container tightly sealed.
Store in cool, dry conditions in well sealed receptacles.
Protect from heat and direct sunlight.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**
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**
- **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:**
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.
Suitable respiratory protective device recommended.
- **Hand protection**



Protective gloves

(Contd. on page 4)

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

(Contd. of page 3)

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	Liquid
· Colour:	Colourless
· Odour:	Odourless
· Melting point/freezing point:	Not determined.
· Boiling point or initial boiling point and boiling range	100 °C (7732-18-5 water, distilled, conductivity or of similar purity)
· Flammability	Not determined
· Lower and upper explosion limit	
· Lower:	Not determined
· Upper:	Not determined
· Flash point:	110 °C (868-77-9 2-hydroxyethyl methacrylate)
· Auto-ignition temperature:	367 °C (868-77-9 2-hydroxyethyl methacrylate)
· Decomposition temperature:	Not applicable.
· pH	Not determined
· Kinematic viscosity	Not determined
· Solubility	
· water:	Soluble.
· Partition coefficient n-octanol/water (log value)	Not applicable.
· Vapour pressure at 20 °C:	23 hPa (7732-18-5 water, distilled, conductivity or of similar purity)
· Density at 20 °C:	1.1 g/cm ³
· Relative vapour density	Not determined
· Particle characteristics	Not applicable.

- **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

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

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· 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** No hazardous reaction when handled and stored according to provisions.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** Carbon monoxide and carbon dioxide

SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.

· **LD/LC50 values relevant for classification:****868-77-9 2-hydroxyethyl methacrylate**

Oral	LD50	4,680 mg/kg (guinea pig)
		3,275 mg/kg (mouse)
		5,050 mg/kg (rat)
Dermal	LD50	5,000 mg/kg (rabbit)

- **Skin corrosion/irritation** Causes skin irritation.
- **Serious eye damage/irritation** Causes serious eye irritation.
- **Respiratory or skin sensitisation** May cause an allergic skin reaction.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **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.

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Trade name: PANAVIA F 2.0 ; ED PRIMER II Liquid A

(Contd. of page 5)

- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable
- **vPvB:** Not applicable
- **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**
Dispose of this product as medical waste.
Mix residues on disposable materials (e.g. paper, tray) and dispose of them as solid waste.
Uncured product residues should be cured before disposal if possible.
- **Uncleaned packaging:**
- **Recommendation:**
Dispose of packaging according to regulations on the disposal of packagings.
Non contaminated packagings may be recycled.
Do not rinse product containers before disposal.

SECTION 14: Transport information

- | | |
|--|----------------|
| · 14.1 UN number or ID number
· ADR, ADN, IMDG, IATA | Void |
| · 14.2 UN proper shipping name
· ADR, ADN, IMDG, IATA | Void |
| · 14.3 Transport hazard class(es)
· ADR, 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.

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

(Contd. of page 6)

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

None of the ingredients is listed.

· **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3· **Regulation (EU) No 649/2012**

None of the ingredients is listed.

· **REGULATION (EU) 2019/1148**· **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

None of the ingredients is listed.

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

None of the ingredients is listed.

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

None of the ingredients is listed.

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

None of the ingredients is listed.

· **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.

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.

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

· **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

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

· **Relevant phrases**

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

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

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 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] (Great Britain (London))+44 20 351 47487, (United Kingdom - Domestic)+44 800 680 0425, (United Kingdom - International)+44 808 189 0979 (Europe Non-Specific)+1 760 476 3962 *Kuraray
Access Code: 334674

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
The product is not classified, according to the GB 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

SECTION 3: Composition/information on ingredients

- **3.2 Mixtures**
- **Description:**
This mixture does not contain any substances to be mentioned according to the criteria of Regulation (EC) No 1272/2008.
- **Dangerous components:** Void

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.

(Contd. on page 2)

Trade name: PANAVIA F 2.0 ; ED PRIMER II Liquid B

(Contd. of page 1)

- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed**
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
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:**
Before cleaning, pre-clean the equipment under running water with a damp cloth.
Avoid disposing of uncured product residues into the sewage system.
- **6.3 Methods and material for containment and cleaning up:**
Dispose contaminated material as waste according to section 13.
Absorb liquid components with liquid-binding material.
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**
Ensure good ventilation/exhaustion at the workplace.
Avoid contact with skin and eyes. Do not swallow. Avoid generating dust. Do not breathe dust/fume/gas/mist/vapors/spray.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store in a refrigerator (2-8°C).
- **Information about storage in one common storage facility:** Not required
- **Further information about storage conditions:**
Keep container tightly sealed.
Store in cool, dry conditions in well sealed receptacles.
Protect from heat and direct sunlight.
- **7.3 Specific end use(s)** No further relevant information available.

GB

(Contd. on page 3)

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

(Contd. of page 2)

SECTION 8: Exposure controls/personal protection· **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**

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

· **Personal protective equipment:**

· **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**

· **Physical state**

Liquid

· **Colour:**

Light yellow

· **Odour:**

Odourless

· **Melting point/freezing point:**

Not determined.

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

100 °C (7732-18-5 water, distilled, conductivity or of similar purity)

· **Flammability**

Not determined

· **Lower and upper explosion limit**

· **Lower:**

Not determined

· **Upper:**

Not determined

· **Flash point:**

>160 °C (Accelerator)

· **Auto-ignition temperature:**

410 °C (Accelerator)

· **Decomposition temperature:**

Not applicable.

· **pH**

Not determined

· **Kinematic viscosity**

Not determined

· **Solubility**

· **water:**

Fully miscible.

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

Not applicable.

· **Vapour pressure at 20 °C:**

23 hPa (7732-18-5 water, distilled, conductivity or of similar purity)

· **Density at 20 °C:**

1 g/cm³

· **Relative vapour density**

Not determined

(Contd. on page 4)

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

(Contd. of page 3)

· Particle characteristics	Not applicable.
· 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 No hazardous reaction when handled and stored according to provisions.
- 10.3 Possibility of hazardous reactions No dangerous reactions known.
- 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.
- 10.6 Hazardous decomposition products: Carbon monoxide and carbon dioxide

SECTION 11: Toxicological information

- 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
- Acute toxicity Based on available data, the classification criteria are not met.
- LD/LC50 values relevant for classification:
- 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.
- 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.

GB

(Contd. on page 5)

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

(Contd. of page 4)

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable
- **vPvB:** Not applicable
- **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **Additional ecological information:**
- **General notes:** Not hazardous for water.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**
Dispose of this product as medical waste.
Mix residues on disposable materials (e.g. paper, tray) and dispose of them as solid waste.
Uncured product residues should be cured before disposal if possible.
- **Uncleaned packaging:**
- **Recommendation:**
Dispose of packaging according to regulations on the disposal of packagings.
Non contaminated packagings may be recycled.
Do not rinse product containers before disposal.

SECTION 14: Transport information

- | | |
|--|----------------|
| · 14.1 UN number or ID number
· ADR, ADN, IMDG, IATA | Void |
| · 14.2 UN proper shipping name
· ADR, ADN, IMDG, IATA | Void |
| · 14.3 Transport hazard class(es)
· ADR, 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 |

GB

(Contd. on page 6)

Trade name: PANAVIA F 2.0 ; ED PRIMER II Liquid B

(Contd. of page 5)

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) 2019/1021 on persistent organic pollutants (POP)

None of the ingredients is listed.

Regulation (EU) No 649/2012

None of the ingredients is listed.

REGULATION (EU) 2019/1148**Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

None of the ingredients is listed.

Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

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

None of the ingredients is listed.

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

None of the ingredients is listed.

- **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.

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.

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

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

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

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] (Great Britain (London))+44 20 351 47487, (United Kingdom - Domestic)+44 800 680 0425, (United Kingdom - International)+44 808 189 0979 (Europe Non-Specific)+1 760 476 3962 *Kuraray
Access Code: 334674

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.
- **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** Void
- **Signal word** Void
- **Hazard statements**
H412 Harmful to aquatic life with long lasting effects.
- **Precautionary statements**
P273 Avoid release to the environment.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Additional Information**
EUH208 Contains benzoyl peroxide. May produce an allergic reaction.
- **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: 94-36-0	benzoyl peroxide	0.1-1%
EINECS: 202-327-6	⚠️ ⚠️ Org. Perox. B, H241; ⚠️ Aquatic Acute 1, H400; Aquatic Chronic 1, H410; ⚠️ Eye Irrit. 2, H319; Skin Sens. 1, H317	

(Contd. on page 2)

Trade name: PANA VIA F 2.0 ; PASTE A

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

(Contd. of page 1)

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed**
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
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:**
Do not allow product to reach sewage system or any water course.
Inform respective authorities in case of seepage into water course or sewage system.
Before cleaning, pre-clean the equipment under running water with a damp cloth.
- **6.3 Methods and material for containment and cleaning up:**
Dispose contaminated material as waste according to section 13.
Absorb liquid components with liquid-binding material.
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**
Ensure good ventilation/exhaustion at the workplace.
Avoid contact with skin and eyes. Do not swallow. Avoid generating dust. Do not breathe dust/fume/gas/mist/vapors/spray.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store in a refrigerator (2-8°C).
- **Information about storage in one common storage facility:** Not required

(Contd. on page 3)

Trade name: PANA VIA F 2.0 ; PASTE A

(Contd. of page 2)

- **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:**

14808-60-7 Quartz (SiO₂)

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

WEL (Great Britain)	Long-term value: 5 mg/m ³
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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

· Physical state	Solid
· Colour:	Colored
· Odour:	Odourless
· Melting point/freezing point:	Not determined.
· Boiling point or initial boiling point and boiling range	Not determined.
· Flammability	Not determined
· Lower and upper explosion limit	
· Lower:	Not applicable.
· Upper:	Not applicable.
· Flash point:	Not applicable

(Contd. on page 4)

Trade name: PANAVIA F 2.0 ; PASTE A

(Contd. of page 3)

· 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 ³
· 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 No hazardous reaction when handled and stored according to provisions.
- 10.3 Possibility of hazardous reactions No dangerous reactions known.
- 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.
- 10.6 Hazardous decomposition products: Carbon monoxide and carbon dioxide

SECTION 11: Toxicological information

- 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
- Acute toxicity Based on available data, the classification criteria are not met.
- LD/LC50 values relevant for classification:
- 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.
- STOT-single exposure Based on available data, the classification criteria are not met.

(Contd. on page 5)

Trade name: PANA VIA F 2.0 ; PASTE A

(Contd. of page 4)

- **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:** Harmful to aquatic life with long lasting effects.
- **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**
- **Remark:** Harmful to fish
- **Additional ecological information:**
- **General notes:**
Not hazardous for water.
Harmful to aquatic organisms

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**
Dispose of this product as medical waste.
Mix residues on disposable materials (e.g. paper, tray) and dispose of them as solid waste.
Uncured product residues should be cured before disposal if possible.
- **Uncleaned packaging:**
- **Recommendation:**
Dispose of packaging according to regulations on the disposal of packagings.
Non contaminated packagings may be recycled.
Do not rinse product containers before disposal.
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)

Trade name: PANA VIA F 2.0 ; PASTE A

(Contd. of page 5)

· 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

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) 2019/1021 on persistent organic pollutants (POP)

None of the ingredients is listed.

· Regulation (EU) No 649/2012

None of the ingredients is listed.

· REGULATION (EU) 2019/1148

· Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

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

None of the ingredients is listed.

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

None of the ingredients is listed.

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

None of the ingredients is listed.

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

[No. 089-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>

(Contd. on page 7)

Trade name: PANA VIA F 2.0 ; PASTE A

(Contd. of page 6)

· **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.

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.

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

· **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

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

· **Relevant phrases**

H241 Heating may cause a fire or explosion.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

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

**Safety data sheet
according to UK REACH**

Printing date 09.04.2025

Version number 9 (replaces version 8)

Revision date: 09.04.2025

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] (Great Britain)+44 20 35147487 (United Kingdom)800 680 0425 (UK English)+44 8 08 189

0979 (Europe Non-Specific)+1 760 476 3962 *Kuraray Access Code: 334674

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

Acute Tox. 4 H302 Harmful if swallowed.

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

Additional information

Medical devices as defined in Regulation (EU) 2017/745 and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (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)

GB

Trade name: PANA VIA F 2.0 ; PASTE B

(Contd. of page 1)

- P280 Wear protective gloves / eye protection / face protection.
 P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
 P330 Rinse mouth.
 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P332+P313 If skin irritation occurs: Get medical advice/attention.
 P362+P364 Take off contaminated clothing and wash it before reuse.
 P337+P313 If eye irritation persists: Get medical advice/attention.
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Additional Information

EUH212 Warning! Hazardous respirable dust may be formed when used. Do not breathe dust.

2.3 Other hazards
Results of PBT and vPvB assessment

• **PBT:** Not applicable.

• **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients
3.2 Mixtures

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

Dangerous components:

CAS: 7681-49-4	sodium fluoride	5-13%
EINECS: 231-667-8	☠ Acute Tox. 3, H301; ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319, EUH032	

SECTION 4: First aid measures
4.1 Description of first aid measures
General information:

Immediately remove any clothing soiled by the product.

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

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

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

After eye contact:

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

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

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures
5.1 Extinguishing media
Suitable extinguishing agents:

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Use fire extinguishing methods suitable to surrounding conditions.

• **5.2 Special hazards arising from the substance or mixture** No further relevant information available.

5.3 Advice for firefighters

• **Protective equipment:** No special measures required.

GB

(Contd. on page 3)

Trade name: PANAVIA F 2.0 ; PASTE B

(Contd. of page 2)

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** See Section 8.
- **6.2 Environmental precautions:** Do not allow product to reach sewage system or any water course.
- **6.3 Methods and material for containment and cleaning up:**
Dispose contaminated material as waste according to section 13.
Contain spill, then place in a suitable container. Minimize dust generation. Do not flush to sewer or allow to enter waterways.
Vacuum or sweep material and place in a disposal container. Provide ventilation.
Use appropriate Personal Protective Equipment (PPE).
- **6.4 Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
Avoid contact with skin and eyes. Do not swallow. Avoid generating dust. Do not breathe dust/fume/gas/mist/vapors/spray.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store in a refrigerator (2-8°C).
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
Keep container tightly sealed.
Store in cool, dry conditions in well sealed receptacles.
Protect from heat and direct sunlight.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection· **8.1 Control parameters**· **Ingredients with limit values that require monitoring at the workplace:****7681-49-4 sodium fluoride**WEL (Great Britain) Long-term value: 2.5 mg/m³
as FIOELV (EU) Long-term value: 2.5 mg/m³
as F**13463-67-7 titanium dioxide**WEL (Great Britain) Long-term value: 10* 4** mg/m³
*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.

(Contd. on page 4)

Trade name: PANA VIA F 2.0 ; PASTE B

(Contd. of page 3)

- **Respiratory protection:** Suitable respiratory protective device recommended.
- **Hand protection**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

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

- **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

- **Penetration time of glove material**

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

- **Eye/face protection**



Tightly sealed goggles

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**

- **General Information**

· Physical state	Solid
· Colour:	Colored
· Odour:	Odourless
· Melting point/freezing point:	Not determined.
· Boiling point or initial boiling point and boiling range	Not determined.
· Flammability	Not determined.
· Lower and upper explosion limit	
· Lower:	Not applicable.
· Upper:	Not applicable.
· Flash point:	Not applicable
· Auto-ignition temperature:	Not applicable.
· Decomposition temperature:	Not applicable.
· pH	Not determined.
· Kinematic viscosity	Not applicable.
· Solubility	
· water:	Insoluble.
· Partition coefficient n-octanol/water (log value)	Not applicable.
· Vapour pressure:	Not applicable.
· Density at 20 °C:	2 g/cm ³
· Relative vapour density	Not applicable.
· Particle characteristics	Not determined.

(Contd. on page 5)

Trade name: PANAVIA F 2.0 ; PASTE B

(Contd. of page 4)

· 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** No hazardous reaction when handled and stored according to provisions.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** Carbon monoxide and carbon dioxide

SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Harmful if swallowed.

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

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

- **Primary irritant effect:**
- **Skin corrosion/irritation** Causes skin irritation.
- **Serious eye damage/irritation** Causes serious eye irritation.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

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**Safety data sheet
according to UK REACH**

Printing date 09.04.2025

Version number 9 (replaces version 8)

Revision date: 09.04.2025

Trade name: PANAVIA F 2.0 ; PASTE B

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· **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:**

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

SECTION 13: Disposal considerations

· **13.1 Waste treatment methods**

· **Recommendation**

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· **Uncleaned packaging:**

· **Recommendation:**

Dispose of packaging according to regulations on the disposal of packagings.

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

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

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

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

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

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

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

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

SECTION 14: Transport information

· **14.1 UN number or ID number**

· **ADR, ADN, IMDG, IATA**

Void

· **14.2 UN proper shipping name**

· **ADR, ADN, IMDG, IATA**

Void

· **14.3 Transport hazard class(es)**

· **ADR, IMDG, IATA**

· **Class**

Void

· **14.4 Packing group**

· **ADR, ADN, IMDG, IATA**

Void

(Contd. on page 7)

Trade name: PANA VIA F 2.0 ; PASTE B

(Contd. of page 6)

· 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>

· **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 Sheets is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2020/878.

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**Safety data sheet
according to UK REACH**

Printing date 09.04.2025

Version number 9 (replaces version 8)

Revision date: 09.04.2025

Trade name: PANA VIA F 2.0 ; PASTE B

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· 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 UK REACH**

Printing date 07.08.2025

Version number 7 (replaces version 6)

Revision date: 07.08.2025

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:** 071
- **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)
[E Company] (Great Britain)+44 20 35147487 (United Kingdom)800 680 0425 (UK English)+44 8 08 189 0979 (Europe Non-Specific)+1 760 476 3962 *Kuraray Access Code: 334674

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
The product is not classified, according to the GB CLP regulation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Additional Information**
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:**
This mixture does not contain any substances to be mentioned according to the criteria of Regulation (EC) No 1272/2008.
- **Dangerous components:** Void

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.

(Contd. on page 2)

**Safety data sheet
according to UK REACH**

Printing date 07.08.2025

Version number 7 (replaces version 6)

Revision date: 07.08.2025

Trade name: PANAVIA F 2.0 ; OXYGUARD II

(Contd. of page 1)

- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed**
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
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:** Do not allow product to reach sewage system or any water course.
- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Dispose contaminated material as waste according to section 13.
Absorb liquid components with liquid-binding material.
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**
Ensure good ventilation/exhaustion at the workplace.
Avoid contact with skin and eyes. Do not swallow. Avoid generating dust. Do not breathe dust/fume/gas/mist/vapors/spray.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store in a refrigerator (2-8°C).
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
Keep container tightly sealed.
Store in cool, dry conditions in well sealed receptacles.
Protect from heat and direct sunlight.
- **7.3 Specific end use(s)** No further relevant information available.

GB

(Contd. on page 3)

Trade name: PANA VIA F 2.0 ; OXYGUARD II

(Contd. of page 2)

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:

56-81-5 Glycerol

WEL (Great Britain) Long-term value: 10 mg/m³

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

Physical state	Liquid
Colour:	Green
Odour:	Odourless
Melting point/freezing point:	Not determined.
Boiling point or initial boiling point and boiling range	290 °C (56-81-5 Glycerol)
Flammability	Not determined.
Lower and upper explosion limit	
Lower:	2.6 Vol % (56-81-5 Glycerol)
Upper:	11.3 Vol % (56-81-5 Glycerol)
Flash point:	160 °C (56-81-5 Glycerol)
Auto-ignition temperature:	400 °C (56-81-5 Glycerol)
Decomposition temperature:	Not applicable.
pH at 20 °C	5.8-6.2
Kinematic viscosity	Not determined.
Solubility	
water:	Fully miscible.
Partition coefficient n-octanol/water (log value)	Not applicable.
Vapour pressure at 20 °C:	<0.1 hPa (56-81-5 Glycerol)
Density:	Not determined.
Relative vapour density	Not determined.

(Contd. on page 4)

Trade name: PANAVIA F 2.0 ; OXYGUARD II

(Contd. of page 3)

· Particle characteristics	Not applicable.
· 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** No hazardous reaction when handled and stored according to provisions.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** Carbon monoxide and carbon dioxide

SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **LD/LC50 values relevant for classification:**
- **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.
- **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.

GB

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**Safety data sheet
according to UK REACH**

Printing date 07.08.2025

Version number 7 (replaces version 6)

Revision date: 07.08.2025

Trade name: PANA VIA F 2.0 ; OXYGUARD II

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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**
- **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.
Dispose of this product as medical waste.
Do not pour product down the drain.
Dispose of product residues with the packaging.
- **Uncleaned packaging:**
- **Recommendation:**
Dispose of packaging according to regulations on the disposal of packagings.
Non contaminated packagings may be recycled.
Do not rinse packaging before disposal.

SECTION 14: Transport information

· 14.1 UN number or ID number · ADR, ADN, IMDG, IATA	Void
· 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA	Void
· 14.3 Transport hazard class(es) · ADR, 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.

(Contd. on page 6)

Trade name: PANAVIA F 2.0 ; OXYGUARD II

(Contd. of page 5)

· 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

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) 2019/1021 on persistent organic pollutants (POP)

None of the ingredients is listed.

· Regulation (EU) No 649/2012

None of the ingredients is listed.

· REGULATION (EU) 2019/1148

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

None of the ingredients is listed.

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

None of the ingredients is listed.

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

None of the ingredients is listed.

· **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.

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.

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

· 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

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

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** 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] (Great Britain (London))+44 20 351 47487, (United Kingdom - Domestic)+44 800 680 0425, (United Kingdom - International)+44 808 189 0979 (Europe Non-Specific)+1 760 476 3962 *Kuraray
Access Code: 334674

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
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.
- **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.
P241 Use explosion-proof [electrical/ventilating/lighting] equipment.

(Contd. on page 2)

Trade name: ALLOY PRIMER

(Contd. of page 1)

- 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.

· **Additional Information**

EUH066 Repeated exposure may cause skin dryness or cracking.

Product contains: Reportable explosives precursors. Making available, introduction, possession and use according to Regulation (EU) 2019/1148, Article 9.

· **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	80-100%
EINECS: 200-662-2	☞ Flam. Liq. 2, H225; ☞ Eye Irrit. 2, H319; STOT SE 3, H336, EUH066	

SECTION 4: First aid measures· **4.1 Description of first aid measures**· **General information:** Immediately remove any clothing soiled by the product.· **After inhalation:** Supply fresh air; consult doctor in case of complaints.· **After skin contact:** Immediately rinse with water.· **After eye contact:**

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

· **After swallowing:** If symptoms persist consult doctor.· **4.2 Most important symptoms and effects, both acute and delayed**

No further relevant information available.

· **4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

SECTION 5: Firefighting measures· **5.1 Extinguishing media**· **Suitable extinguishing agents:**CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.· **For safety reasons unsuitable extinguishing agents:** Water with full jet· **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.

GB

(Contd. on page 3)

Trade name: ALLOY PRIMER

(Contd. of page 2)

SECTION 6: Accidental release measures**· 6.1 Personal precautions, protective equipment and emergency procedures**

Wear protective equipment. Keep unprotected persons away.

See Section 8.

· 6.2 Environmental precautions:

Prevent seepage into sewage system, workpits and cellars.

Before cleaning, pre-clean the equipment under running water with a damp cloth.

· 6.3 Methods and material for containment and cleaning up:

Dispose contaminated material as waste according to section 13.

Ensure adequate ventilation.

Absorb liquid components with liquid-binding material.

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**

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

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:

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:** Not required**· Further information about storage conditions:**

Keep container tightly sealed.

Store in cool, dry conditions in well sealed receptacles.

Protect from heat and direct sunlight.

· 7.3 Specific end use(s) No further relevant information available.**SECTION 8: Exposure controls/personal protection****· 8.1 Control parameters****· Ingredients with limit values that require monitoring at the workplace:****67-64-1 acetone**WEL (Great Britain) Short-term value: 3620 mg/m³, 1500 ppm
Long-term value: 1210 mg/m³, 500 ppmIOELV (EU) Long-term value: 1210 mg/m³, 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 section 7.**· Personal protective equipment:****· General protective and hygienic measures:**

Keep away from foodstuffs, beverages and feed.

(Contd. on page 4)

Trade name: ALLOY PRIMER

(Contd. of page 3)

Immediately remove all soiled and contaminated clothing
 Wash hands before breaks and at the end of work.
 Avoid contact with the eyes.
 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.
 Suitable respiratory protective device recommended.

Hand protection


Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
 Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

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

Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material

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

Eye/face protection


Tightly sealed goggles

SECTION 9: Physical and chemical properties
9.1 Information on basic physical and chemical properties
General Information

· Physical state	Liquid
· Colour:	Colourless
· Odour:	Acetone-like
· Melting point/freezing point:	Not determined.
· Boiling point or initial boiling point and boiling range	56 °C (67-64-1 acetone)
· Flammability	Highly flammable.
· Lower and upper explosion limit	
· Lower:	2.2 Vol % (67-64-1 acetone)
· Upper:	13 Vol % (67-64-1 acetone)
· Flash point:	-18 °C (67-64-1 acetone)
· Auto-ignition temperature:	538 °C (67-64-1 acetone)
· Decomposition temperature:	Not applicable.
· pH	Not determined
· Kinematic viscosity	Not determined
· Solubility	
· water:	Not determined
· Partition coefficient n-octanol/water (log value)	Not applicable.

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Trade name: ALLOY PRIMER

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· Vapour pressure at 20 °C:	247 hPa (67-64-1 acetone)
· Density:	Not determined
· Relative vapour density	Not determined
· Particle characteristics	Not applicable.

· 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	Highly flammable liquid and vapour.
· 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** No hazardous reaction when handled and stored according to provisions.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** Carbon monoxide and carbon dioxide

SECTION 11: Toxicological information· **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**

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

· **LD/LC50 values relevant for classification:****67-64-1 acetone**

Oral	LD50	5,800 mg/kg (rat)
Dermal	LD50	20,000 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.

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· **11.2 Information on other hazards**· **Endocrine disrupting properties**

None of the ingredients is listed.

SECTION 12: Ecological information· **12.1 Toxicity**· **Aquatic toxicity:** No further relevant information available.· **12.2 Persistence and degradability** No further relevant information available.· **12.3 Bioaccumulative potential** No further relevant information available.· **12.4 Mobility in soil** No further relevant information available.· **12.5 Results of PBT and vPvB assessment**· **PBT:** Not applicable· **vPvB:** Not applicable· **12.6 Endocrine disrupting properties**

The product does not contain substances with endocrine disrupting properties.

· **12.7 Other adverse effects**· **Additional ecological information:**· **General notes:**

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

SECTION 13: Disposal considerations· **13.1 Waste treatment methods**· **Recommendation**

Dispose of this product as medical waste.

Mix residues on disposable materials (e.g. paper, tray) and dispose of them as solid waste.

· **Uncleaned packaging:**· **Recommendation:**

Dispose of packaging according to regulations on the disposal of packagings.

Non contaminated packagings may be recycled.

Do not rinse product containers before disposal.

SECTION 14: Transport information· **14.1 UN number or ID number**· **ADR, IMDG, IATA**

UN1090

· **14.2 UN proper shipping name**· **ADR**

1090 ACETONE mixture

· **IMDG, IATA**

ACETONE mixture

· **14.3 Transport hazard class(es)**· **ADR, IMDG, IATA**· **Class**

3 Flammable liquids.

· **Label**

3

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· 14.4 Packing group · ADR, IMDG, IATA	II
· 14.5 Environmental hazards:	Not applicable
· 14.6 Special precautions for user · Hazard identification number (Kemler code): · EMS Number: · Stowage Category	Warning: Flammable liquids. 33 F-E,S-D E
· 14.7 Maritime transport in bulk according to IMO instruments	Not applicable
· Transport/Additional information:	
· ADR · Limited quantities (LQ) · Excepted quantities (EQ)	1L Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· Transport category · Tunnel restriction code	2 D/E
· IMDG · Limited quantities (LQ) · Excepted quantities (EQ)	1L Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· UN "Model Regulation":	UN 1090 ACETONE MIXTURE, 3, II

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

67-64-1 acetone

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.

· Seveso category P5c 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) 2019/1021 on persistent organic pollutants (POP)

None of the ingredients is listed.

· REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

· Regulation (EU) No 649/2012

None of the ingredients is listed.

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· **REGULATION (EU) 2019/1148**· **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

67-64-1 acetone

· **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

3

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

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.

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.

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

· **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

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

· **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.

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