



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

- **1.1 Product identifier**
- **Trade name:** PANAVIA V5 ; Paste
- **Article number:** 214-P
- **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** Resin-based dental adhesive cement
- **1.3 Details of the supplier of the safety data sheet**
- **Supplier :**
Kuraray Europe GmbH
Philipp-Reis-Str. 4,
65795 Hattersheim am Main
Germany
Phone: +49 (0)69 305 35 835
E-mail: dental.eu@kuraray.com
- **Further information obtainable from:** Supplier
- **1.4 Emergency telephone number:**
(UK) 0 800 680 0425
(GB) +44 20 35147487
(AU) +61 2 80363166
* 3E Company
* Kuraray Access Code:334674

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2 H319 Causes serious eye irritation.
Carc. 2 H351 Suspected of causing cancer. Route of exposure: Inhalation.
- **Additional information**
Medical devices as defined in Regulation (EU) 2017/745 and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (GB CLP/ GHS) usually if they are in the finished state and intended for the final user.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the GB CLP regulation.
- **Hazard pictograms**
 
GHS07 GHS08
- **Signal word** Warning
- **Hazard-determining components of labelling:**
titanium dioxide
- **Hazard statements**
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H351 Suspected of causing cancer. Route of exposure: Inhalation.
- **Precautionary statements**
P264 Wash thoroughly after handling.

(Contd. on page 2)

Trade name: PANAVIA V5 ; Paste

(Contd. of page 1)

- P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
- P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P308+P313 IF exposed or concerned: Get medical advice/attention.
- P321 Specific treatment (see on this label).
- P362+P364 Take off contaminated clothing and wash it before reuse.
- P332+P313 If skin irritation occurs: Get medical advice/attention.
- P337+P313 If eye irritation persists: Get medical advice/attention.
- P405 Store locked up.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

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

- **Precautionary statements**

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: 1565-94-2 EINECS: 216-367-7	bisphenol A diglycidylmethacrylate ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319	5-15%
CAS: 109-16-0 EINECS: 203-652-6	Triethyleneglycol dimethacrylate ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	<5%
CAS: 13463-67-7 EINECS: 236-675-5	titanium dioxide ⚠ Carc. 2, H351	<5%

- **Other ingredients:**

Silanated barium glass filler
Hydrophobic aromatic dimethacrylate
Silanated fluoroalminosilicate glass filler
Hydrophilic aliphatic dimethacrylate
Silanated alumina filler
Accelerators
Initiator
Amorphous silica
dl-Camphorquinone
Pigment

- **Additional information:**

Aluminium oxide; Nanoform, Silanated alumina, particle size 1 - 100 nm
Silicon oxide; Nanoform, Amorphous silica, particle size 1 - 100 nm

SECTION 4: First aid measures

- **4.1 Description of first aid measures**

- **General information:**

Avoid contact with eyes.

Avoid contact with skin.

- **After inhalation:** Supply fresh air; consult doctor in case of complaints.

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

(Contd. on page 3)

Trade name: PANAVIA V5 ; Paste

(Contd. of page 2)

- **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.
- **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 to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Pick up mechanically. Ensure adequate ventilation.
- **6.4 Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** No special precautions are necessary if used correctly.
- **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 item 7.
- **Personal protective equipment:**
- **General protective and hygienic measures:** Wash hands before breaks and at the end of work.

(Contd. on page 4)

Trade name: PANA VIA V5 ; Paste

(Contd. of page 3)

- **Respiratory protection:** Not required.
- **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:	According to product specification
· 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 determined
· Upper:	Not determined
· Flash point:	Not determined
· Auto-ignition temperature:	Not determined
· Decomposition temperature:	Not determined
· pH	Not determined
· Viscosity:	Not determined
· Solubility	
· water:	Insoluble.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not determined.
· Density and/or relative density	
· Density:	1.8 g/cm ³
· Relative density	Not determined
· Relative vapour density	Not determined
· Particle characteristics	See item 3.

(Contd. on page 5)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 28.04.2023

Version number 4

Revision date: 28.04.2023

Trade name: PANAVIA V5 ; Paste

(Contd. of page 4)

· 9.2 Other information	
· Appearance:	
· Form:	Pasty
· Important information on protection of health and environment, and on safety.	
· Explosive properties:	Product does not present an explosion hazard.
· Change in condition	
· Softening point/range	
· Oxidising properties	Not determined.
· Evaporation rate	Not determined
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** Carbon monoxide and carbon dioxide

SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Skin corrosion/irritation** Causes skin irritation.
- **Serious eye damage/irritation** Causes serious eye irritation.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity**
Suspected of causing cancer. Route of exposure: Inhalation.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

(Contd. on page 6)

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

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Trade name: PANA VIA V5 ; Paste

(Contd. of page 5)

· **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:**

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

SECTION 13: Disposal considerations

· **13.1 Waste treatment methods**

· **Recommendation**

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

· **Uncleaned packaging:**

· **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

· **14.1 UN number or ID number**

· **ADR, ADN, IMDG, IATA** Void

· **14.2 UN proper shipping name**

· **ADR, ADN, IMDG, IATA** Void

· **14.3 Transport hazard class(es)**

· **ADR, ADN, IMDG, IATA**

· **Class** Void

· **14.4 Packing group**

· **ADR, IMDG, IATA** Void

· **14.5 Environmental hazards:**

· **Marine pollutant:** No

· **14.6 Special precautions for user**

Not applicable.

· **14.7 Maritime transport in bulk according to IMO instruments**

Not applicable.

· **UN "Model Regulation":**

Void

GB

(Contd. on page 7)

Trade name: PANAVIA V5 ; Paste

(Contd. of page 6)

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 94/33/EC:** Care should be taken when people under 18 handle this product.
- **Directive 94/85/EEC:** No further relevant information available.
- **Chemical safety assessment**
- **Named dangerous substances - ANNEX I** None of the ingredient is listed.
- **Regulation (EU) No 649/2012**

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

None of the ingredients is listed.

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

None of the ingredients is listed.

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

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Relevant phrases**

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H351 Suspected of causing cancer.

· **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

Carc. 2: Carcinogenicity – Category 2

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

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