

Printing date 12.10.2021 Version number 3 (replaces version 2)

Revision date: 12.10.2021

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 35835 E-mail: dental.eu@kuraray.com

· Further information obtainable from: Supplier

· 1.4 Emergency telephone number:

(UK) 08006800425 (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 Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

Hazard pictograms





GHS07

GHS08

- · Signal word Warning
- · Hazard-determining components of labelling:

bisphenol A diglycidylmethacrylate triethylene glycol dimethacrylate 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.

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P280 Wear protective gloves/protective clothing/eye protection/face protection.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

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.

· 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:			
		5-15%	
EINECS: 216-367-7	♦ Skin Irrit. 2, H315; Eye Irrit. 2, H319		
	Triethyleneglycol dimethacrylate	<5%	
EINECS: 203-652-6	♦ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335		
	titanium dioxide	<5%	
EINECS: 236-675-5	♦ Carc. 2, H351, EUH212		

· Other ingredients:

Silanated barium glass filler

Silanated fluoroalminosilicate glass filler

Colloidal silica

Surface treated aluminum oxide filler

Hydrophobic aromatic dimethacrylate

Hydrophobic aliphatic dimethacrylate

dl-Camphorquinone

Initiators

Accelerators

Pigments

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.
- · After eve 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.

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• 4.3 Indication of any immediate medical attention and special treatment needed No further relevant information available.

SECTION 5: Firefighting measures

- · 5.1 Extinguishing media
- · Suitable extinguishing agents:
- CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- · 5.3 Advice for firefighters
- · Protective equipment: 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.
- · 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.
- · Individual protection measures, such as personal protective equipment
- · General protective and hygienic measures: Wash hands before breaks and at the end of work.
- · Respiratory protection: Not required.

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· 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.

· Eve/face protection



Tightly sealed goggles

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

Colored
 Odour:
 Melting point/freezing point:
 Colored
 Odourless
 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:
Decomposition temperature:
Not determined

·Solubility

• water: Insoluble.
• Partition coefficient n-octanol/water (log value) Not determined.

• Vapour pressure: Not determined.

· Density and/or relative density

Density:

Density:

Relative density

Vapour density

Particle characteristics

1.8 g/cm³

Not determined

Not determined

See item 3.

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· 9.2 Other information

· Appearance:

· Form: Pasty

· Important information on protection of health and environment, and on safety.

· Ignition temperature:

Not determined

· 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

Void gases in contact with water · Oxidising liquids Void · Oxidising solids Void Void · Organic peroxides Void · Corrosive to metals Void · Desensitised explosives

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 irriation.
- · 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.

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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:

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 instruments	g to IMO Not applicable.		
· UN "Model Regulation":	Void		

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

SECTION 16: Other information

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

· Abbreviations and acronyms:

ELINCS: European List of Notified Chemical Substances

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.

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