

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

Version number 3 (replaces version 2)

Revision date: 11.10.2021



· 1.1 Product identifier

• Trade name: PANAVIA V5 ; Try-in Paste

- · Article number: 214-Ti
- **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 colour matching test material

- · 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) 0 800 680 0425
 (CB) +44 20 25147487
- (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

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



· Signal word Warning

· Hazard-determining components of labelling:

Glycerin

titanium dioxide

· Hazard statements

H351 Suspected of causing cancer. Route of exposure: Inhalation.

· Precautionary statements

- P201 Obtain special instructions before use.
- P202 Do not handle until all safety precautions have been read and understood.
- P280 Wear protective gloves/protective clothing/eye protection/face protection.
- P308+P313 IF exposed or concerned: Get medical advice/attention.
- P405 Store locked up.

(Contd. on page 2)

GB



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Revision date: 11.10.2021

Trade name: PANAVIA V5 ; Try-in Paste

(Contd. of page 1) 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: 56-81-5 EINECS: 200-289-5	Glycerin	substance with a Community workplace exposure limit	75-95%	
CAS: 13463-67-7 EINECS: 236-675-5	titanium dioxide	🗞 Carc. 2, H351, EUH212	<5%	
Other ingredients: Polyethyleneglycol Silanated silica filler Silanated colloidal si Colloidal silica Pigments	lica			

SECTION 4: First aid measures

· 4.1 Description of first aid measures

• After inhalation: Supply fresh air and to be sure call for a doctor.

- After skin contact: Generally the product does not irritate the skin.
- After eye contact: Rinse opened eye for several minutes under running water.

• After swallowing: If symptoms persist consult doctor.

• 4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

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

No further relevant information available.

SECTION 5: Firefighting measures

· 5.1 Extinguishing media

• Suitable extinguishing agents: Use fire extinguishing methods suitable to surrounding conditions.

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

• 5.3 Advice for firefighters

· Protective equipment: No special measures required.

SECTION 6: Accidental release measures

• 6.1 Personal precautions, protective equipment and emergency procedures See Section 8.

• 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water. • 6.3 Methods and material for containment and cleaning up: Pick up mechanically.

(Contd. on page 3)

GB



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Revision date: 11.10.2021

Trade name: PANAVIA V5 ; Try-in Paste

(Contd. of page 2)

• 6.4 Reference to other sections No dangerous substances are released.

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling No special measures required.

· Information about fire - and explosion protection: No special measures required.

· 7.2 Conditions for safe storage, including any incompatibilities

· Storage:

• Requirements to be met by storerooms and receptacles: Store in a cool location (2-25°C).

- · Information about storage in one common storage facility: Not required.
- Further information about storage conditions: Store in cool, dry conditions in well sealed receptacles.
- Keep container tightly sealed.

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:

56-81-5 Glycerin

WEL 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 item 7.
- · Individual protection measures, such as personal protective equipment
- General protective and hygienic measures:
- The usual precautionary measures are to be adhered to when handling chemicals.

• 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 Goggles recommended during refilling

 SECTION 9: Physical and chemical properties

 • 9.1 Information on basic physical and chemical properties

 • General Information

 • Colour:
 Coloured

 • Odour:
 Odourless



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Trade name: PANAVIA V5 ; Try-in Paste

	(Contd. of page
Melting point/freezing point:	18.2 °C (glycerol)
Boiling point or initial boiling point and boiling	
range	290.0 °C (glycerol)
Lower and upper explosion limit	
Lower:	0.9 Vol % (glycerol)
Upper:	Not determined
Flash point:	160 °C (glycerol)
Decomposition temperature:	Not determined
рН	Not determined
Viscosity:	Not determined
Solubility	
water:	Partly soluble.
Partition coefficient n-octanol/water (log value)	Not determined
Vapour pressure:	0.1 hPa (20°C, glycerol)
	0.1 m a (20°C, gryceror)
Density and/or relative density	1.2 g/om^3
Density:	1.2 g/cm ³
Relative density	Not determined
Vapour density	Not determined
Particle characteristics	See item 3.
9.2 Other information	
Appearance:	
Form:	Pasty
Important information on protection of health an	
environment, and on safety.	
Ignition temperature:	400.0 °C (glycerol)
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
	Void
Gases under pressure	Void
Flammable liquids	
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
	Void
Oxidising liquids	, ord
Oxidising liquids Oxidising solids	Void
Oxidising solids	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.

(Contd. on page 5)

GB



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Version number 3 (replaces version 2)

Revision date: 11.10.2021

Trade name: PANAVIA V5 ; Try-in Paste

· 10.6 Hazardous decomposition products: Carbon monoxide and carbon dioxide

(Contd. of page 4)

SECTION 11: Toxicological information

 \cdot 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

 \cdot Acute toxicity Based on available data, the classification criteria are not met.

- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- Serious eye damage/irritation Based on available data, the classification criteria are not met.
- Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity
- 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.
- \cdot Aspiration hazard Based on available data, the classification criteria are not met.
- 11.2 Information on other hazards

· Endocrine disrupting properties

None of the ingredients is listed.

SECTION 12: Ecological information

- · 12.1 Toxicity
- Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- 12.4 Mobility in soil No further relevant information available.
- · 12.5 Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- · vPvB: Not applicable.
- 12.6 Endocrine disrupting properties For information on endocrine disrupting properties see section 11.
- · 12.7 Other adverse effects
- · Additional ecological information:
- · General notes:

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

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation Smaller quantities can be disposed of with household waste.
- · Uncleaned packaging:
- Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

[.] 14.1 UN number or ID number

· ADR, ADN, IMDG, IATA

• 14.2 UN proper shipping name • ADR, ADN, IMDG, IATA

Void

Void

(Contd. on page 6)

GB -



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Trade name: PANAVIA V5 ; Try-in Paste

	(Contd. of page 5
Void	
Void	
No	
Not applicable.	
g to IMO Not applicable	
Void	
	No Not applicable. g to IMO Not applicable.

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
- Carc. 2: Carcinogenicity Category 2
- * Data compared to the previous version altered.