

Printing date 29.09.2016 Version number 2 Revision: 29.09.2016

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

· Manufacturer:

Kuraray Europe GmbH Philipp-Reis-Str. 4,

65795 Hattersheim am Main

Germany

Phone:+49 (0)69 305 35 840 Fax:+49 (0)69 305 35 640 E-mail: dental@kuraray.de

· Supplier:

J & S Davis

5 Whitworth Road, Stevenage,

Hertfordshir, SG1 4QS

Great Britain

Tel: +44- (0) 1438 747344 Fax: +44- (0)1438 758909 E-mail: jsdsales@js-davis.co.uk

· Further information obtainable from: Manufacturer or Supplier

1.4 Emergency telephone number:

National Poisons information Service (London Centre)

Guy's & St. Thomas' Hospital Trust

Medical Toxicology Unit

Avonley Road LONDON SE14 5ER

Emergency telephone: (local) 0870 600 6266 or +44 20 7771 5394

Administrative telephone: +44 20 7 771 53 10 Facsimile number: +44 20 7 771 53 09

SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
- Classification according to Regulation (EC) No 1272/2008



GHS07

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

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

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

- · Hazard pictograms GHS07
- · Signal word Warning
- · Hazard statements

H315 Causes skin irritation.

H319 Causes serious eye irritation.

(Contd. on page 2)



Printing date 29.09.2016 Version number 2 Revision: 29.09.2016

Trade name: PANAVIA V5; Paste

(Contd. of page 1)

Precautionary statements

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

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

present and easy to do. Continue rinsing.

P321 Specific treatment (see on this label).

P332+P313 If skin irritation occurs: Get medical advice/attention. P337+P313 If eye irritation persists: Get medical advice/attention.

P302+P352 IF ON SKIN: Wash with plenty of water.

P362+P364 Take off contaminated clothing and wash it before reuse.

· Labelling of packages where the contents do not exceed 125 ml

· Hazard-determining components of labelling:

bisphenol A diglycidylmethacrylate triethyleneglycol dimethacrylate

- · 2.3 Other hazards
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable. · **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

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

ſ	· Dangerous compone	ents:	
ſ	CAS: 1565-94-2	0 - 0 p - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 -	5-15%
	EINECS: 216-367-7	♦ Skin Irrit. 2, H315; Eye Irrit. 2, H319	
ſ		triethylene glycol dimethacrylate	<5%
	EINECS: 203-652-6	♦ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	

Other ingredients:

Silanated barium glass filler

Silanated fluoroalminosilicate glass filler

Colloidal silica

Surface treated aluminum oxide filler

Hydrophobic aromatic dimethacrylate

Hydrophilic 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 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.

(Contd. on page 3)



Printing date 29.09.2016 Version number 2 Revision: 29.09.2016

Trade name: PANAVIA V5; Paste

(Contd. of page 2)

4.3 Indication of any immediate medical attention and special treatment neededNo 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

- · Additional information about design of technical facilities: No further data; see item 7.
- · 8.1 Control parameters
- Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

- · Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures: Wash hands before breaks and at the end of work.
- Respiratory protection: Not required.

(Contd. on page 4)



Printing date 29.09.2016 Version number 2 Revision: 29.09.2016

Trade name: PANAVIA V5; Paste

(Contd. of page 3)

· Protection of hands:



Protective gloves

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

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

· Material of gloves

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

Penetration time of glove material

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

· Eye protection: Safety glasses

SECTION 9: Physical and ch	nemical properties	
9.1 Information on basic physical and chemical properties		
General Information		
Appearance:	_	
Form:	Pasty	
Colour:	Coloured	
· Odour:	Odourless	
pH-value:	Not determined	
Change in condition		
Melting point/Melting range:	Not determined	
Boiling point/Boiling range:	Not determined	
· Flash point:	Not determined	
Flammability (solid, gaseous):	Not determined	
· Ignition temperature:		
Decomposition temperature:	Not determined	
Self-igniting:	Not determined	
Danger of explosion:	Product does not present an explosion hazard.	
Explosion limits:		
Lower:	Not determined	
Upper:	Not determined	
Vapour pressure:	Not determined	
Density:	1.8 g/cm ³	
Relative density	Not determined	
Vapour density	Not determined	
Evaporation rate	Not determined	
Solubility in / Miscibility with		
water:	Insoluble.	

(Contd. on page 5)



Printing date 29.09.2016 Version number 2 Revision: 29.09.2016

Trade name: PANAVIA V5; Paste

(Contd. of page 4)

· Partition coefficient (n-octanol/water): Not determined.

• Viscosity: Not determined

• **9.2 Other information** No further relevant information available.

SECTION 10: Stability and reactivity

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

SECTION 11: Toxicological information

- 11.1 Information on toxicological effects
- · Acute toxicity Based on available data, the classification criteria are not met.
- 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.
- · Acute effects (acute toxicity) Not applicable
- CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- Germ cell mutagenicity Based on available data, the classification criteria are not met.
- Carcinogenicity Based on available data, the classification criteria are not met.
- Reproductive toxicity Based on available data, the classification criteria are not met.
- · STOT-single exposure Based on available data, the classification criteria are not met.
- STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- · 12.1 Toxicity
- Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- 12.4 Mobility in soil No further relevant information available.
- Additional ecological information:
- · General notes:

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

- · 12.5 Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · **vPvB**: Not applicable.
- 12.6 Other adverse effects No further relevant information available.

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Printing date 29.09.2016 Version number 2 Revision: 29.09.2016

Trade name: PANAVIA V5; Paste

(Contd. of page 5)

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 informa	ation
· 14.1 UN-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 Transport in bulk according to Ann Marpol and the IBC Code	nex II of Not applicable.
· UN "Model Regulation":	Void

SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture No further relevant information available.
- · 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Relevant phrases

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

Abbreviations and acronyms:

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

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

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

* Data compared to the previous version altered.



Printing date 29.09.2016 Version number 2 Revision: 29.09.2016

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

· 1.1 Product identifier

Trade name: PANAVIA V5; Tooth Primer

· Article number: 214-TP

· 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 bonding material

· 1.3 Details of the supplier of the safety data sheet

· Manufacturer:

Kuraray Europe GmbH Philipp-Reis-Str. 4,

65795 Hattersheim am Main

Germany

Phone:+49 (0)69 305 35 840 Fax:+49 (0)69 305 35 640 E-mail: dental@kuraray.de

· Supplier:

J & S Davis

5 Whitworth Road, Stevenage,

Hertfordshir, SG1 4QS

Great Britain

Tel: +44- (0) 1438 747344 Fax: +44- (0)1438 758909 E-mail: jsdsales@js-davis.co.uk

· Further information obtainable from: Manufacturer or Supplier

1.4 Emergency telephone number:

National Poisons information Service (London Centre)

Guy's & St. Thomas' Hospital Trust

Medical Toxicology Unit

Avonley Road LONDON SE14 5ER

Emergency telephone: (local) 0870 600 6266 or +44 20 7771 5394

Administrative telephone: +44 20 7 771 53 10 Facsimile number: +44 20 7 771 53 09

SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
- Classification according to Regulation (EC) No 1272/2008



GHS07

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

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

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

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

- · Hazard pictograms GHS07
- Signal word Warning
- · Hazard-determining components of labelling:

2-hydroxyethyl methacrylate

(Contd. on page 2)



Printing date 29.09.2016 Version number 2 Revision: 29.09.2016

Trade name: PANAVIA V5; Tooth Primer

(Contd. of page 1)

· Hazard statements

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

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

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

present and easy to do. Continue rinsing.

P321 Specific treatment (see on this label).
P363 Wash contaminated clothing before reuse.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention. P337+P313 If eye irritation persists: Get medical advice/attention.

P302+P352 IF ON SKIN: Wash with plenty of water.

P362+P364 Take off contaminated clothing and wash it before reuse.

P501 Dispose of contents/container in accordance with local/regional/national/international

regulations.

· 2.3 Other hazards

· Results of PBT and vPvB assessment

· **PBT:** Not applicable. · **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

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

Dangerous components:

CAS: 868-77-9 | 2-hydroxyethyl methacrylate | 25-50% EINECS: 212-782-2 | Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317

Other ingredients:

10-Methacryloyloxydecyl dihydrogen phosphate

Hydrophilic aliphatic dimethacrylate

Accelerators

Water

SECTION 4: First aid measures

- 4.1 Description of first aid measures
- General information:

Avoid contact with eves.

Avoid contact with skin.

· 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.

GB



Printing date 29.09.2016 Version number 2 Revision: 29.09.2016

Trade name: PANAVIA V5; Tooth Primer

(Contd. of page 2)

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:**

Dilute with plenty of water.

Do not allow to enter sewers/ surface or ground water.

· 6.3 Methods and material for containment and cleaning up:

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

Ensure adequate ventilation.

6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

-7.1 Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

- · Information about fire and explosion protection: No special measures required.
- 7.2 Conditions for safe storage, including any incompatibilities
- Storage:
- Requirements to be met by storerooms and receptacles: Store in a refrigerator (2-8 °C).
- · Information about storage in one common storage facility: 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

- Additional information about design of technical facilities: No further data; see item 7.
- · 8.1 Control parameters
- Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

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

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

(Contd. on page 4)



Printing date 29.09.2016 Version number 2 Revision: 29.09.2016

Trade name: PANAVIA V5; Tooth Primer

(Contd. of page 3)

Avoid contact with the eyes and skin.

Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

Protection of hands:



Protective gloves

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

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

· Material of gloves

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

· Penetration time of glove material

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

Eye protection:

Oxidising properties



Tightly sealed goggles

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties · General Information		
· Appearance:		
Form:	Liquid	
Colour:	Light blue	
· Odour:	Odourless	
· pH-value:	<2.3	
· Change in condition		
Melting point/Melting range:	Not determined	
Boiling point/Boiling range:	205 °C (2-hydroxyethyl methacrylate)	
· Flash point:	97 °C (2-hydroxyethyl methacrylate)	
· Ignition temperature:	Not determined	
Decomposition temperature:	Not determined	
· Self-igniting:	Not determined	
· Danger of explosion:	Product does not present an explosion hazard.	
· Explosion limits:		
Lower:	Not determined	
Upper:	Not determined	

Not determined

(Contd. on page 5)



Printing date 29.09.2016 Version number 2 Revision: 29.09.2016

Trade name: PANAVIA V5; Tooth Primer

		(Contd. of page 4
· Vapour pressure:	Not determined	
Density:	1.1 g/cm³	
Relative density	Not determined	
· Vapour density	Not determined	
Evaporation rate	Not determined	
Solubility in / Miscibility with		
water:	Fully miscible.	
Partition coefficient (n-octanol	/water): Not determined	
· Viscosity:	Not determined	
9.2 Other information	No further relevant information available.	

SECTION 10: Stability and reactivity

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

SECTION 11: Toxicological information

- 11.1 Information on toxicological effects
- · Acute toxicity Based on available data, the classification criteria are not met.
- · LD/LC50 values relevant for classification:

868-77-9 2-hydroxyethyl methacrylate

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

- Primary irritant effect:
- · Skin corrosion/irritation

Causes skin irritation.

· Serious eye damage/irritation

Causes serious eye irritation.

Respiratory or skin sensitisation

May cause an allergic skin reaction.

- · Acute effects (acute toxicity) Not applicable
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- · Reproductive toxicity Based on available data, the classification criteria are not met.
- STOT-single exposure Based on available data, the classification criteria are not met.
- STOT-repeated exposure Based on available data, the classification criteria are not met.
- Aspiration hazard Based on available data, the classification criteria are not met.

GB



Printing date 29.09.2016 Version number 2 Revision: 29.09.2016

Trade name: PANAVIA V5; Tooth Primer

(Contd. of page 5)

SECTION 12: Ecological information

- · 12.1 Toxicity
- Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- 12.4 Mobility in soil No further relevant information available.
- Additional ecological information:
- · General notes:

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

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

- · 12.5 Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · **vPvB:** Not applicable.
- 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- Recommendation

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

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

SECTION 14: Transport informa	tion	
· 14.1 UN-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 Transport in bulk according to Ann Marpol and the IBC Code	nex II of Not applicable.	
· UN "Model Regulation":	Void	

SECTION 15: Regulatory information

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

(Contd. on page 7)



Printing date 29.09.2016 Version number 2 Revision: 29.09.2016

Trade name: PANAVIA V5; Tooth Primer

(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.

· Relevant phrases

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

· Abbreviations and acronyms:

Skin Irrit. 2: Skin corrosion/irritation – Category 2 Eye Irrit. 2: Serious eye damage/eye irritation – Category 2 Skin Sens. 1: Skin sensitisation – Category 1

* Data compared to the previous version altered.

CD.



Printing date 26.07.2016 Version number 2 Revision: 26.07.2016

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

· 1.1 Product identifier

Trade name: CLEARFIL CERAMIC PRIMER PLUS

· Article number: 215

· Registration number Not applicable

· 1.2 Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

· Application of the substance / the mixture Adhesive, dental ceramic/ Adhesive, dental metal

· 1.3 Details of the supplier of the safety data sheet

· Manufacturer:

Kuraray Europe GmbH Philipp-Reis-Str. 4,

65795 Hattersheim am Main

Germany

Phone:+49 (0)69 305 35 840 Fax:+49 (0)69 305 35 640 E-mail: dental@kuraray.de

· Supplier:

J & S Davis

5 Whitworth Road, Stevenage,

Hertfordshir, SG1 4QS

Great Britain

Tel: +44- (0) 1438 747344 Fax: +44- (0)1438 758909 E-mail: jsdsales@js-davis.co.uk

Further information obtainable from: Manufacturer or Supplier

1.4 Emergency telephone number:

National Poisons information Service (London Centre)

Guy's & St. Thomas' Hospital Trust

Medical Toxicology Unit

Avonley Road LONDON SE14 5ER

Emergency telephone: (local) 0870 600 6266 or +44 20 7771 5394

Administrative telephone: +44 20 7 771 53 10 Facsimile number: +44 20 7 771 53 09

SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
- Classification according to Regulation (EC) No 1272/2008



GHS02 flame

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

- · 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 GHS02
- · Signal word Danger
- · Hazard statements

H225 Highly flammable liquid and vapour.

Precautionary statements

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No

smoking.

P241 Use explosion-proof electrical/ventilating/lighting/equipment.

(Contd. on page 2)



Printing date 26.07.2016 Version number 2 Revision: 26.07.2016

Trade name: CLEARFIL CERAMIC PRIMER PLUS

(Contd. of page 1)

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

P240 Ground/bond container and receiving equipment.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with

water/shower.

P370+P378 In case of fire: Use for extinction: CO2, powder or water spray.

P501 Dispose of contents/container in accordance with local/regional/national/international

regulations.

· Labelling of packages where the contents do not exceed 125 ml

· Hazard-determining components of labelling:

ethanol

3-trimethoxysilylpropyl methacrylate

- · 2.3 Other hazards
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable. · **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- · 3.1 Chemical characterisation: Substances None
- 3.2 Chemical characterisation: Mixtures
- **Description:** Mixture of substances listed below with nonhazardous additions.

· Dangerous compone	ents:	
	ethanol	>80%
EINECS: 200-578-6	◈ Flam. Liq. 2, H225	
	3-trimethoxysilylpropyl methacrylate	< 5%
EINECS: 219-785-8	♦ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	

· Other ingredients: 10-Methacryloyloxydecyl dihydrogen phosphate

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- · After inhalation: Supply fresh air; consult doctor in case of complaints.
- · After skin contact: Immediately rinse with water.
- After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.
- · After swallowing:

Do not induce vomiting; call for medical help immediately.

If symptoms persist consult doctor.

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

No further relevant information available.

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

No further relevant information available.

SECTION 5: Firefighting measures

- 5.1 Extinguishing media
- · Suitable extinguishing agents:

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:

Wear self-contained respiratory protective device.

(Contd. on page 3)



Printing date 26.07.2016 Version number 2 Revision: 26.07.2016

Trade name: CLEARFIL CERAMIC PRIMER PLUS

(Contd. of page 2)

Wear fully protective suit.

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

6.2 Environmental precautions:

Dilute with plenty of water.

Do not allow to enter sewers/ surface or ground water.

· 6.3 Methods and material for containment and cleaning up:

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

Ensure adequate ventilation.

6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

- 7.1 Precautions for safe handling Ensure good ventilation/exhaustion at the workplace.
- · 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 refrigerator (2-8 °C).
- Information about storage in one common storage facility:

Store away from oxidising agents.

Store away from reducing agents.

· Further information about storage conditions:

Keep container tightly sealed.

Store in cool, dry conditions in well sealed receptacles.

Protect from heat and direct sunlight.

· 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- · Additional information about design of technical facilities: No further data; see item 7.
- · 8.1 Control parameters
- Ingredients with limit values that require monitoring at the workplace:

64-17-5 ethanol

WEL Long-term value: 1920 mg/m³, 1000 ppm

- Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Personal protective equipment:
- General protective and hygienic measures: Wash hands before breaks and at the end of work.
- Respiratory protection: Not required.
- · Protection of hands:

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

(Contd. on page 4)



Printing date 26.07.2016 Version number 2 Revision: 26.07.2016

Trade name: CLEARFIL CERAMIC PRIMER PLUS

(Contd. of page 3)

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 protection:



Tightly sealed goggles

SECTION 9: P	hysical and	l chemical	properties
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9.1 Information on basic physical a	nd chemical properties
General Information	
Appearance: Form:	Liquid
Colour:	Colourless
· Odour:	Alcohol-like
pH-value:	Not determined
· Change in condition	
Melting point/Melting range:	-114.5 °C (ethanol)
Boiling point/Boiling range:	78 °C (ethanol)
	,
Flash point:	13 °C (ethanol)
Ignition temperature:	425.0 °C (ethanol)
Decomposition temperature:	Not determined
Danger of explosion:	Product is not explosive. However, formation of explosive air/
	vapour mixtures are possible.
Explosion limits:	
Lower:	3.5 Vol % (ethanol)
Upper:	15.0 Vol % (ethanol)
Oxidising properties	Not determined
Vapour pressure:	59.0 hPa (20 °C, ethanol)
Density:	0.8 g/cm ³
Relative density	Not determined
Vapour density	1.6 g/cm³ (ethanol, air=1)
Evaporation rate	Not determined
Solubility in / Miscibility with	
water:	Partly miscible.
Partition coefficient (n-octanol/wate	er): -0.32 (ethanol)
Viscosity:	Not determined

(Contd. on page 5)



Printing date 26.07.2016 Version number 2 Revision: 26.07.2016

Trade name: CLEARFIL CERAMIC PRIMER PLUS

(Contd. of page 4)

• **9.2 Other information** No further relevant information available.

SECTION 10: Stability and reactivity

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

SECTION 11: Toxicological information

- 11.1 Information on toxicological effects
- · Acute toxicity Based on available data, the classification criteria are not met.

· LD/LC50	values rel	evant for classification:
64-17-5 et	hanol	
Oral	LD50	3450 mg/kg (mouse)
		7060 mg/kg (rat)
Inhalative	LC50/4 h	20000 mg/l (rat)
	LD50	3600 mg/kg (rat - intraperioneal)
2530-85-0	3-trimeth	oxysilylpropyl methacrylate
Oral	LD50	22600 mg/kg (rat)
Dermal	LD50	500 mg/kg (rabbit)

- Primary irritant effect:
- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- Serious eve damage/irritation Based on available data, the classification criteria are not met.
- Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- Reproductive toxicity Based on available data, the classification criteria are not met.
- STOT-single exposure Based on available data, the classification criteria are not met.
- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- 12.4 Mobility in soil No further relevant information available.
- Additional ecological information:
- General notes:

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

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

- · 12.5 Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.

(Contd. on page 6)



Printing date 26.07.2016 Version number 2 Revision: 26.07.2016

Trade name: CLEARFIL CERAMIC PRIMER PLUS

(Contd. of page 5)

• 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- Recommendation

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

- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.
- Recommended cleansing agents: Water, if necessary together with cleansing agents.

SECTION 14: Transport informa	tion
14.1 UN-Number ADR, IMDG, IATA	1170
14.2 UN proper shipping name	
ADR	1170 ETHANOL (ETHYL ALCOHOL), mixture
IMDG	ETHANOL (ETHYL ALCOHOL), mixture
IATA	ETHANOL, mixture
14.3 Transport hazard class(es)	
ADR, IMDG, IATA	
Class Label	3 Flammable liquids.
14.4 Packing group ADR, IMDG, IATA	II
14.5 Environmental hazards:	
Marine pollutant:	No
14.6 Special precautions for user	Warning: Flammable liquids.
Danger code (Kemler):	33
EMS Number:	F-E,S-D
14.7 Transport in bulk according to Ann	nex II of
Marpol and the IBC Code	Not applicable.
UN "Model Regulation":	UN1170; ETHANOL (ETHYL ALCOHOL), mixture:

SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

GB



Printing date 26.07.2016 Version number 2 Revision: 26.07.2016

Trade name: CLEARFIL CERAMIC PRIMER PLUS

(Contd. of page 6)

SECTION 16: Other information

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

· Relevant phrases

H225 Highly flammable liquid and vapour.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

· Abbreviations and acronyms:

Flam. Liq. 2: Flammable liquids – Category 2 Skin Irrit. 2: Skin corrosion/irritation – Category 2

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

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

* Data compared to the previous version altered.

C.D.



Printing date 10.08.2016 Version number 2 Revision: 10.08.2016

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

· 1.1 Product identifier

Trade name: K-ETCHANT Syringe

· Article number: 197

· 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 etching composite

· 1.3 Details of the supplier of the safety data sheet

· Manufacturer:

Kuraray Europe GmbH Philipp-Reis-Str. 4,

65795 Hattersheim am Main

Germany

Phone:+49 (0)69 305 35 840 Fax:+49 (0)69 305 35 640 E-mail: dental@kuraray.de

· Supplier:

J & S Davis

5 Whitworth Road, Stevenage,

Hertfordshir, SG1 4QS

Great Britain

Tel: +44- (0) 1438 747344 Fax: +44- (0)1438 758909 E-mail: jsdsales@js-davis.co.uk

· Further information obtainable from: Manufacturer or Supplier

· 1.4 Emergency telephone number:

National Poisons information Service (London Centre)

Guy's & St. Thomas' Hospital Trust

Medical Toxicology Unit

Avonley Road LONDON **SE14 5ER**

Emergency telephone: (local) 0870 600 6266 or +44 20 7771 5394

Administrative telephone: +44 20 7 771 53 10 Facsimile number: +44 20 7 771 53 09

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008



GHS05 corrosion

Skin Corr. 1B H314 Causes severe skin burns and eye damage.

- · 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 GHS05
- · Signal word Danger
- · Hazard-determining components of labelling:

phosphoric acid

· Hazard statements

H314 Causes severe skin burns and eye damage.

(Contd. on page 2)



Printing date 10.08.2016 Version number 2 Revision: 10.08.2016

Trade name: K-ETCHANT Syringe

(Contd. of page 1)

· Precautionary statements

P264 Wash thoroughly after handling.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with

water/shower.

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

present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER/doctor.

P362 Take off contaminated clothing.

P363 Wash contaminated clothing before reuse.

P405 Store locked up.

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

 Dangerous 	components:
-------------------------------	-------------

CAS: 7664-38-2 phosphoric acid EINECS: 231-633-2

Skin Corr. 1B, H314

25-45%

Other ingredients:

Polyethyleneglycol

Colloidal silica Water

Pigment

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- General information: Immediately remove any clothing soiled by the product.
- 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 eve contact: Rinse opened eye for several minutes under running water. Then consult a doctor.
- After swallowing: Drink plenty of water and provide fresh air. 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.

- 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.

(Contd. on page 3)



Printing date 10.08.2016 Version number 2 Revision: 10.08.2016

Trade name: K-ETCHANT Syringe

Wear fully protective suit.

(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.

6.2 Environmental precautions:

Dilute with plenty of water.

Do not allow to enter sewers/ surface or ground water.

· 6.3 Methods and material for containment and cleaning up:

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

Use neutralising agent.

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

· 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

- 7.1 Precautions for safe handling Ensure good ventilation/exhaustion at the workplace.
- 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:

Store away from oxidising agents.

Store away from reducing agents.

· Further information about storage conditions:

Keep container tightly sealed.

Store in cool, dry conditions in well sealed receptacles.

Protect from heat and direct sunlight.

· 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- · Additional information about design of technical facilities: No further data; see item 7.
- · 8.1 Control parameters
- Ingredients with limit values that require monitoring at the workplace:

7664-38-2 phosphoric acid

WEL Short-term value: 2 mg/m³ Long-term value: 1 mg/m³

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

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

(Contd. on page 4)



Printing date 10.08.2016 Version number 2 Revision: 10.08.2016

Trade name: K-ETCHANT Syringe

(Contd. of page 3)

Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

Protection of hands:



Protective gloves

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

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

· Material of gloves

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

· Penetration time of glove material

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

· Eye protection:



Tightly sealed goggles

SECTION 9: Physical and chemical properties

9.1 Information on basic physical a	nd chemical properties
General Information	
· Appearance: Form:	Gel
Colour:	Blue
· Odour:	Odourless
· pH-value:	1.9
Change in condition Melting point/Melting range: Boiling point/Boiling range:	42.4 °C (phosphoric acid) Not determined
· Flash point:	Not determined
· Ignition temperature:	Not determined
Decomposition temperature:	Not determined
Danger of explosion:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined
Upper:	Not determined
· Oxidising properties	Not determined
· Vapour pressure:	Not determined
· Density:	1.3 g/cm ³
Relative density	Not determined

(Contd. on page 5)



Printing date 10.08.2016 Version number 2 Revision: 10.08.2016

Trade name: K-ETCHANT Syringe

(Contd. of page 4

		(Conta. of page 4)
· Vapour density	Not determined	
Evaporation rate	Not determined	
· Solubility in / Miscibility with		
water:	Partly miscible.	
· Partition coefficient (n-octano	l/water): Not determined	
· Viscosity:	Not determined	
9.2 Other information	No further relevant information available.	

SECTION 10: Stability and reactivity

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

SECTION 11: Toxicological information

- · 11.1 Information on toxicological effects
- · Acute toxicity Based on available data, the classification criteria are not met.

· LD/LC50 value	es relevant for	classification:
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7664-38-2 phosphoric acid

Oral	LD50	1250 mg/kg (mouse)
		1250 mg/kg (rat)
Dermal		2740 mg/kg (rabbit)

- · Primary irritant effect:
- · Skin corrosion/irritation

Causes severe skin burns and eye damage.

Serious eye damage/irritation

Causes severe skin burns and eye damage.

- Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- Reproductive toxicity Based on available data, the classification criteria are not met.
- · STOT-single exposure Based on available data, the classification criteria are not met.
- STOT-repeated exposure Based on available data, the classification criteria are not met.
- Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- 12.4 Mobility in soil No further relevant information available.

(Contd. on page 6)



Printing date 10.08.2016 Version number 2 Revision: 10.08.2016

Trade name: K-ETCHANT Syringe

(Contd. of page 5)

- · 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. Must not reach sewage water or drainage ditch undiluted or unneutralised.

Rinse off of bigger amounts into drains or the aquatic environment may lead to decreased pH-values. A low pH-value harms aquatic organisms. In the dilution of the use-level the pH-value is considerably increased, so that after the use of the product the aqueous waste, emptied into drains, is only low water-dangerous.

- · 12.5 Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- Recommendation

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

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

SECTION 14: Transport informa	tion
14.1 UN-Number ADR, IMDG, IATA	1805
14.2 UN proper shipping name ADR IMDG, IATA	1805 PHOSPHORIC ACID, SOLUTION PHOSPHORIC ACID, SOLUTION
14.3 Transport hazard class(es)	
ADR, IMDG, IATA	
<u>\$1</u>	
Class	8 Corrosive substances.
Label	8
14.4 Packing group ADR, IMDG, IATA	III
14.5 Environmental hazards:	
Marine pollutant:	No
14.6 Special precautions for user	Warning: Corrosive substances.
Danger code (Kemler):	80
EMS Number:	F-A,S-B
14.7 Transport in bulk according to Ann	nex II of
Marpol and the IBC Code	Not applicable.
UN "Model Regulation":	UN1805; PHOSPHORIC ACID, SOLUTION; 8; III



Printing date 10.08.2016 Version number 2 Revision: 10.08.2016

Trade name: K-ETCHANT Syringe

(Contd. of page 6)

SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
- · 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

· Relevant phrases

H314 Causes severe skin burns and eye damage.

Abbreviations and acronyms:

Skin Corr. 1B: Skin corrosion/irritation – Category 1B

* Data compared to the previous version altered.

GB



Printing date 12.10.2016 Version number 2 Revision: 12.10.2016

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

· 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

· Manufacturer:

Kuraray Europe GmbH Philipp-Reis-Str. 4,

65795 Hattersheim am Main

Germany

Phone:+49 (0)69 305 35 840 Fax:+49 (0)69 305 35 640 E-mail: dental@kuraray.de

· Supplier:

J & S Davis

5 Whitworth Road, Stevenage,

Hertfordshir, SG1 4QS

Great Britain

Tel: +44- (0) 1438 747344 Fax: +44- (0)1438 758909 E-mail: jsdsales@js-davis.co.uk

· Further information obtainable from: Manufacturer or Supplier

· 1.4 Emergency telephone number:

National Poisons information Service (London Centre)

Guy's & St. Thomas' Hospital Trust

Medical Toxicology Unit

Avonley Road LONDON **SE14 5ER**

Emergency telephone: (local) 0870 600 6266 or +44 20 7771 5394

Administrative telephone: +44 20 7 771 53 10 Facsimile number: +44 20 7 771 53 09

SECTION 2: Hazards identification

- 2.1 Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008

The product is not classified according to the CLP regulation.

- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008 Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · 2.3 Other hazards
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.



Version number 2 Revision: 12.10.2016 Printing date 12.10.2016

Trade name: PANAVIA V5 Try-in Paste

(Contd. of page 1)

SECTION 3: Composition/information on ingredients

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

Dangerous components:

CAS: 56-81-5 EINECS: 200-289-5

glycerol

substance with a Community workplace exposure limit 75-95%

Other ingredients:

Polyethyleneglycol

Silanated silica filler

Silanated colloidal silica

Colloidal silica

Pigments

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 eve 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.
- · 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
- 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.

(Contd. on page 3)



Printing date 12.10.2016 Version number 2 Revision: 12.10.2016

Trade name: PANAVIA V5 Try-in Paste

(Contd. of page 2)

Protect from heat and direct sunlight.

• 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- · Additional information about design of technical facilities: No further data; see item 7.
- · 8.1 Control parameters
- · Ingredients with limit values that require monitoring at the workplace:

56-81-5 glycerol

WEL Long-term value: 10 mg/m³

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

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

- Respiratory protection: Not required.
- Protection of hands:

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

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

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

· Material of gloves

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

Penetration time of glove material

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

· Eye protection: Goggles recommended during refilling

SECTION 9: Physical and chemical properties

 9.1 Information on basic physical at General Information Appearance: 	nd chemical properties
Form:	Pasty
Colour: · Odour:	Coloured Odourless
· pH-value:	Not determined
· Change in condition Melting point/Melting range: Boiling point/Boiling range:	18.2 °C (glycerol) 290 °C (glycerol)
· Flash point:	160 °C (glycerol)
· Ignition temperature:	400.0 °C (glycerol)
Decomposition temperature:	Not determined
Danger of explosion:	Product does not present an explosion hazard.

(Contd. on page 4)



Printing date 12.10.2016 Version number 2 Revision: 12.10.2016

Trade name: PANAVIA V5 Try-in Paste

		(Contd. of page
Explosion limits:		
Lower:	0.9 Vol % (glycerol)	
Upper:	Not determined	
Oxidising properties	Not determined	
Vapour pressure:	0.1 hPa (20 °C, glycerol)	
Density:	1.2 g/cm ³	
Relative density	Not determined	
Vapour density	Not determined	
Evaporation rate	Not determined	
Solubility in / Miscibility with		
water:	Partly soluble.	
Partition coefficient (n-octanol/	water): Not determined	
Viscosity:	Not determined	
9.2 Other information	No further relevant information available.	

SECTION 10: Stability and reactivity

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

SECTION 11: Toxicological information

- 11.1 Information on toxicological effects
- · Acute toxicity Based on available data, the classification criteria are not met.
- · Primary irritant effect:
- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- Acute effects (acute toxicity) Not classified
- CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- · Reproductive toxicity Based on available data, the classification criteria are not met.
- STOT-single exposure Based on available data, the classification criteria are not met.
- STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- · 12.1 Toxicity
- Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- 12.4 Mobility in soil No further relevant information available.

(Contd. on page 5)



Printing date 12.10.2016 Version number 2 Revision: 12.10.2016

Trade name: PANAVIA V5 Try-in Paste

(Contd. of page 4)

- · Additional ecological information:
- General notes:

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

- · 12.5 Results of PBT and vPvB assessment
- · **PBT**: Not applicable.
- · vPvB: Not applicable.
- 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

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

SECTION 14: Transport informa	ation	
· 14.1 UN-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 Transport in bulk according to Ann Marpol and the IBC Code	nex II of Not applicable.	
UN "Model Regulation":	Void	

SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture No further relevant information available.
- · 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

* Data compared to the previous version altered.

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