

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,
Hertfordshire, 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.

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Trade name: PANAVIA V5 ; Paste

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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.

Dangerous components:

CAS: 1565-94-2 EINECS: 216-367-7	bisphenol A diglycidylmethacrylate ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319	5-15%
CAS: 109-16-0 EINECS: 203-652-6	triethylene glycol dimethacrylate ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	<5%

Other ingredients:

Silanated barium glass filler
 Silanated fluoroaluminosilicate 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.

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Trade name: PANAVIA V5 ; Paste

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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

- **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.

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Trade name: PANAVIA V5 ; Paste

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· **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 through 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 chemical 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.

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Trade name: PANAVIA V5 ; Paste

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- | |
|---------------------------------------------------------------------------|
| · 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 (carcinogenicity, 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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Trade name: PANAVIA V5 ; Paste

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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
· 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 Annex II of Marpol and the IBC Code | 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.**

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

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Trade name: PANAVIA V5 ; Tooth Primer

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· **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 eyes.
- 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

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

Printing date 29.09.2016

Version number 2

Revision: 29.09.2016

Trade name: PANAVIA V5 ; Tooth Primer

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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.

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GB

Trade name: PANAVIA V5 ; Tooth Primer

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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 through 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 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

· **Oxidising properties** Not determined

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Trade name: PANAVIA V5 ; Tooth Primer

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· Vapour pressure:	Not determined
· Density:	1.1 g/cm ³
· 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 (carcinogenicity, 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

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

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Trade name: PANAVIA V5 ; Tooth Primer

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SECTION 12: Ecological information

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

<ul style="list-style-type: none"> · 14.1 UN-Number · ADR, ADN, IMDG, IATA 	Void
<ul style="list-style-type: none"> · 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA 	Void
<ul style="list-style-type: none"> · 14.3 Transport hazard class(es) · ADR, ADN, IMDG, IATA · Class 	Void
<ul style="list-style-type: none"> · 14.4 Packing group · ADR, IMDG, IATA 	Void
<ul style="list-style-type: none"> · 14.5 Environmental hazards: · Marine pollutant: 	No
<ul style="list-style-type: none"> · 14.6 Special precautions for user 	Not applicable.
<ul style="list-style-type: none"> · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code 	Not applicable.
<ul style="list-style-type: none"> · 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

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Trade name: PANAVIA V5 ; Tooth Primer

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· **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.**

GB

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,
Hertfordshire, 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.

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- 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 components:**

CAS: 64-17-5	ethanol	>80%
EINECS: 200-578-6	Flam. Liq. 2, H225	
CAS: 2530-85-0	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.

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Wear fully protective suit.

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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.

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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 and 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/cm ³ (ethanol, air=1)
· Evaporation rate	Not determined

· **Solubility in / Miscibility with water:** Partly miscible.

· **Partition coefficient (n-octanol/water):** -0.32 (ethanol)

· **Viscosity:** Not determined

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· **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:**

64-17-5 ethanol

Oral	LD50	3450 mg/kg (mouse) 7060 mg/kg (rat)
Inhalative	LC50/4 h	20000 mg/l (rat)
	LD50	3600 mg/kg (rat - intraperitoneal)

2530-85-0 3-trimethoxysilylpropyl 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 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.
- **CMR effects (carcinogenicity, 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.

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· **12.6 Other adverse effects** No further relevant information available.

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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 information

· **14.1 UN-Number**

· **ADR, IMDG, IATA**

1170

· **14.2 UN proper shipping name**

· **ADR**

· **IMDG**

· **IATA**

1170 ETHANOL (ETHYL ALCOHOL), mixture

ETHANOL (ETHYL ALCOHOL), mixture

ETHANOL, mixture

· **14.3 Transport hazard class(es)**

· **ADR, IMDG, IATA**



· **Class**

3 Flammable liquids.

· **Label**

3

· **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 Annex II of Marpol and the IBC Code**

Not applicable.

· **UN "Model Regulation":**

UN1170; ETHANOL (ETHYL ALCOHOL), mixture; 3; II

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.

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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.