


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

- **1.1 Product identifier**
- **Trade name:** PANAVIA Veneer LC
- **Article number:** 236
- **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 Adhesive Resin Cement System
- **1.3 Details of the supplier of the safety data sheet**
- **Supplier :**
Kuraray Europe GmbH
Philipp-Reis-Str. 4,
65795 Hattersheim am Main
Germany
Phone:+49 (0)69 305 35835
E-mail: dental.eu@kuraray.com
- **Further information obtainable from:** Supplier
- **1.4 Emergency telephone number:**
(UK) 0 800 680 0425
(GB) +44 20 35147487
(AU) +61 2 80363166
* 3E Company
* Kuraray Access Code:334674

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
 - **Classification according to Regulation (EC) No 1272/2008**
Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2 H319 Causes serious eye irritation.
 - **Additional information :**
Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.
 - **2.2 Label elements**
 - **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the CLP regulation.
 - **Hazard pictograms**
- 

GHS07
- **Signal word** Warning
 - **Hazard-determining components of labelling:**
Surface treated ytterbium trifluoride
triethylene glycol dimethacrylate
 - **Hazard statements**
H315 Causes skin irritation.
H319 Causes serious eye irritation.
 - **Precautionary statements**
P264 Wash thoroughly after handling.
P280 Wear protective gloves / eye protection / face protection.
P302+P352 IF ON SKIN: Wash with plenty of water.

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Safety data sheet

according to 1907/2006/EC, Article 31

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Trade name: PANA VIA Veneer LC

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- P321 Specific treatment (see on this label).
 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P332+P313 If skin irritation occurs: Get medical advice/attention.
 P362+P364 Take off contaminated clothing and wash it before reuse.
 P337+P313 If eye irritation persists: Get medical advice/attention.
- **2.3 Other hazards**
 - **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

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

- **Dangerous components:**

CAS: 13760-80-0 EINECS: 237-354-2	ytterbium trifluoride	>5%
CAS: 109-16-0 EINECS: 203-652-6	Triethyleneglycol dimethacrylate ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	>5%

- **Other ingredients:**

Silanated nano-spherical silica filler
 Hydrophilic amide monomer
 Hydrophobic aliphatic dimethacrylate
 dl-Camphorquinone
 Initiators
 Accelerators
 Pigments

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 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.

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.

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Trade name: PANA VIA Veneer LC

(Contd. of page 2)

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** See Section 8.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Pick up mechanically. Ensure adequate ventilation.
- **6.4 Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** No special precautions are necessary if used correctly.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store in a refrigerator (2-8°C).
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
Keep container tightly sealed.
Store in cool, dry conditions in well sealed receptacles.
Protect from heat and direct sunlight.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:** Wash hands before breaks and at the end of work.
- **Respiratory protection:** Not required.
- **Hand protection**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**

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

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Trade name: PANAVIA Veneer LC

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- **Penetration time of glove material**
The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye/face protection**



Tightly sealed goggles

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Colour:	Coloured
· Odour:	Odourless
· Melting point/freezing point:	Not determined
· Boiling point or initial boiling point and boiling range	Not determined
· Flammability	Not determined
· Lower and upper explosion limit	
· Lower:	Not determined
· Upper:	Not determined
· Flash point:	Not determined
· Auto-ignition temperature:	Not determined
· Decomposition temperature:	Not determined
· pH	Not determined
· Viscosity:	Not determined
· Solubility	
· water:	Insoluble.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not determined.
· Density and/or relative density	
· Density:	1.8 g/cm ³
· Relative density	Not determined
· Vapour density	Not determined
· Particle characteristics	See item 3.

· 9.2 Other information

· Appearance:	
· Form:	Pasty
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Not determined
· Explosive properties:	Product does not present an explosion hazard.
· Change in condition	
· Softening point/range	
· Oxidising properties	Not determined.
· Evaporation rate	Not determined
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void

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Trade name: PANAVIA Veneer LC

(Contd. of page 4)

· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

SECTION 10: Stability and reactivity

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

SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity**
Void
- **Skin corrosion/irritation** Causes skin irritation.
- **Serious eye damage/irritation** Causes serious eye irritation.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity**
Void
- **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**
Void
- **11.2 Information on other hazards**

- **Endocrine disrupting properties**

None of the ingredients is listed.

SECTION 12: Ecological information

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

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Trade name: PANAVIA Veneer LC

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- **Additional ecological information:**
- **General notes:**
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- | | |
|---|-----------------|
| · 14.1 UN number or ID number
· ADR, ADN, IMDG, IATA | Void |
| · 14.2 UN proper shipping name
· ADR, ADN, IMDG, IATA | Void |
| · 14.3 Transport hazard class(es)
· ADR, ADN, IMDG, IATA
· Class | Void |
| · 14.4 Packing group
· ADR, IMDG, IATA | Void |
| · 14.5 Environmental hazards:
· Marine pollutant: | No |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Maritime transport in bulk according to IMO instruments | Not applicable. |
| · UN "Model Regulation": | Void |

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 94/33/EC:** Care should be taken when people under 18 handle this product.
- **Directive 94/85/EEC:** No further relevant information available.
- **Chemical safety assessment**
- **Named dangerous substances - ANNEX I** None of the ingredient is listed.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

- **Abbreviations and acronyms:**
ELINCS: European List of Notified Chemical Substances
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

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,
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**



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.

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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	 Skin Corr. 1B, H314	25-45%
EINECS: 231-633-2			

· **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 eye 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.

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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/m ³ Long-term value: 1 mg/m ³
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- **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.

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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 and chemical properties**

· **General Information**

· **Appearance:**

· Form:	Gel
· Colour:	Blue
· Odour:	Odourless

· **pH-value:** 1.9

· **Change in condition**

· Melting point/Melting range:	42.4 °C (phosphoric acid)
· Boiling point/Boiling range:	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/cm³

· **Relative density** Not determined

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Trade name: K-ETCHANT Syringe

(Contd. of page 4)

· Vapour density	Not determined
· Evaporation rate	Not determined
· Solubility in / Miscibility with water:	Partly 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:**

7664-38-2 phosphoric acid

Oral	LD50	1250 mg/kg (mouse)
		1250 mg/kg (rat)
Dermal	LD50	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 (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.

(Contd. on page 6)

Trade name: K-ETCHANT Syringe


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- **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 information

- | | |
|---|---|
| · 14.1 UN-Number | |
| · ADR, IMDG, IATA | 1805 |
| · 14.2 UN proper shipping name | |
| · ADR | 1805 PHOSPHORIC ACID, SOLUTION |
| · IMDG, IATA | PHOSPHORIC ACID, SOLUTION |
| · 14.3 Transport hazard class(es) | |
| · ADR, IMDG, IATA | |
|  | |
| · 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 Annex II of Marpol and the IBC Code | Not applicable. |
| · UN "Model Regulation": | UN1805; PHOSPHORIC ACID, SOLUTION; 8; III |

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(Contd. on page 7)

Trade name: K-ETCHANT Syringe

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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

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**

1170 ETHANOL (ETHYL ALCOHOL), mixture

· **IMDG**

ETHANOL (ETHYL ALCOHOL), mixture

· **IATA**

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.