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

Printing date 04.02.2015 Revision: 06.01.2015

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
· **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.
· **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
F; Highly flammable

R11: Highly flammable.
· **Information concerning particular hazards for human and environment:**
The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
· **Classification system:**
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

· **2.2 Label elements**
· **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the CLP regulation.

(Contd. on page 2)

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

Printing date 04.02.2015 Revision: 06.01.2015

Trade name: CLEARFIL CERAMIC PRIMER PLUS

(Contd. of page 1)

· **Hazard pictograms** GHS02
· **Signal word** Danger
· **Hazard statements**
H225 Highly flammable liquid and vapour.
· **Precautionary statements**

P210	Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
P241	Use explosion-proof electrical/ventilating/lighting/equipment.
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): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
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: 64-17-5 EINECS: 200-578-6	ethanol F R11 Flam. Liq. 2, H225	>80%
CAS: 2530-85-0 EINECS: 219-785-8	3-trimethoxysilylpropyl methacrylate Xi R36/37/38 Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	< 5%

· **Other ingredients:** 10-Methacryloyloxydecyl dihydrogen phosphate

SECTION 4: 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)

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

Printing date 04.02.2015 Revision: 06.01.2015

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**
· **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.
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

(Contd. on page 4)

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

Printing date 04.02.2015 Revision: 06.01.2015

Trade name: CLEARFIL CERAMIC PRIMER PLUS

(Contd. of page 3)

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 applicable
· **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)
· **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)
· **Vapour pressure:**	59.0 hPa (20 °C, ethanol)
· **Density:**	0.8 g/cm³
· **Vapour density**	1.6 g/cm³ (ethanol, air=1)
· **Solubility in / Miscibility with water:**	Partly miscible.
· **Partition coefficient (n-octanol/water):**	-0.32 (ethanol)
· **9.2 Other information**	No further relevant information available.

SECTION 10: Stability and reactivity

· **10.1 Reactivity**
· **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

(Contd. on page 5)

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

Printing date 04.02.2015 Revision: 06.01.2015

Trade name: CLEARFIL CERAMIC PRIMER PLUS

(Contd. of page 4)

SECTION 11: Toxicological information

· **11.1 Information on toxicological effects**
· **Acute toxicity:**

· **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 - intraperioneal)
2530-85-0 3-trimethoxysilylpropyl methacrylate		
Oral	LD50	22600 mg/kg (rat)
Dermal	LD50	500 mg/kg (rabbit)

· **Primary irritant effect:**
· **on the skin:** No irritant effect
· **on the eye:** No irritating effect
· **Sensitisation:** No sensitising effects known.
· **Acute effects (acute toxicity)** Not classified

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

· **14.1 UN-Number**	
· **ADR, IMDG, IATA**	1170
· **14.2 UN proper shipping name**	
· **ADR**	1170 ETHANOL (ETHYL ALCOHOL), mixture

(Contd. on page 6)

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

Printing date 04.02.2015 Revision: 06.01.2015

Trade name: CLEARFIL CERAMIC PRIMER PLUS

(Contd. of page 5)

· **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 MARPOL73/78 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**
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.

· **Version:** 1
· **Relevant phrases**
H225 Highly flammable liquid and vapour.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.

R11 Highly flammable.
R36/37/38 Irritating to eyes, respiratory system and skin.
· **Abbreviations and acronyms:**
Flam. Liq. 2: Flammable liquids, Hazard Category 2
Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2
STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3