

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

- **Product identifier**
- **Trade name:** CLEARFIL CERAMIC PRIMER
- **Article number:** US117
- **Application of the substance / the preparation** Adhesive, dental ceramic
- **Details of the supplier of the safety data sheet**
- **Manufacturer:**
Kuraray Medical Inc.
1621 Sakazu, Kurashiki, Okayama 710-0801,
Japan
- **Supplier:**
Kuraray America, Inc.
600 Lexington Avenue, 26th Floor, New York,
NY 10022 U.S.A.
Tel: 800-879-1676
Fax: 888-700-5200
Website: www.kuraraydental.com

2 Composition/information on ingredients

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

· **Dangerous components:**

64-17-5	ethanol	H225	>80%
2530-85-0	3-trimethoxysilylpropyl methacrylate	H315; H319; H335; H227	< 5%

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

3 Hazards identification

- **Classification of the substance or mixture**



GHS02 Flame

H225 Highly flammable liquid and vapour.

- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**



Highly flammable

Highly flammable.

- **Information concerning particular hazards for human and environment:**

The product has to be labelled due to the calculation procedure of international guidelines.

- **Classification system:**

The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

- **Label elements**

- **GHS label elements**

The product is classified and labelled according to the Globally Harmonized System (GHS).

- **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.

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- 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.

- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



Health = 0
Fire = 3
Reactivity = 0

- **HMIS-ratings (scale 0 - 4)**



Health = 0
Fire = 3
Reactivity = 0

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; immediately call for medical help.
If symptoms persist consult doctor.

5 Firefighting measures

- **Suitable extinguishing agents:**
CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Protective equipment:**
Wear self-contained respiratory protective device.
Wear fully protective suit.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:**
Dilute with plenty of water.
Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Ensure adequate ventilation.
- **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.

7 Handling and storage

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

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- **Information about protection against explosions and fires:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
- **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 oxidizing agents.
Store away from reducing agents.
- **Further information about storage conditions:**
Keep receptacle tightly sealed.
Store in cool, dry conditions in well sealed receptacles.
Protect from heat and direct sunlight.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.

- **Components with limit values that require monitoring at the workplace:**

64-17-5 ethanol

PEL	1900 mg/m ³ , 1000 ppm
REL	1900 mg/m ³ , 1000 ppm
TLV	1880 mg/m ³ , 1000 ppm

- **Additional information:** The lists that were valid during the creation were used as basis.
- **Personal protective equipment:**
- **General protective and hygienic measures:** Wash hands before breaks and at the end of work.
- **Breathing equipment:** Not required.
- **Protection of hands:**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- **Penetration time of glove material**
The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:**



Tightly sealed goggles

9 Physical and chemical properties

- **General Information**
- **Appearance:**
 - Form:** Liquid
 - Color:** Colorless
- **Odor:** Alcohol-like

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· 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/vapor mixtures are possible.
· Explosion limits:	
Lower:	3.5 Vol % (ethanol)
Upper:	15.0 Vol % (ethanol)
· Vapor pressure:	59.0 hPa (20°C, ethanol)
· Density:	1.1 g/cm ³
· Vapour density	1.6 g/cm ³ (ethanol, air=1)
· Solubility in / Miscibility with	
Water:	Partly miscible.
· Segregation coefficient (n-octanol/water):	-0.32 (ethanol)

10 Stability and reactivity

- **Thermal decomposition / conditions to be avoided:**
No decomposition if used and stored according to specifications.
- **Hazardous decomposition products:** Carbon monoxide and carbon dioxide

11 Toxicological information

- **Acute toxicity:**

- **LD/LC50 values that are 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:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.

12 Ecological information

- **Acquatic toxicity:** No further relevant information available.

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- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (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.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport information

· **DOT regulations:**



- **Hazard class:** 3
- **Identification number:** UN1170
- **Packing group:** II
- **Proper shipping name (technical name):** ETHANOL, mixture
- **Label:** 3

· **Land transport ADR/RID (cross-border):**



- **ADR/RID class:** 3 Flammable liquids
- **Danger code (Kemler):** 33
- **UN-Number:** 1170
- **Packaging group:** II
- **Label:** 3
- **UN proper shipping name:** 1170 ETHANOL (ETHYL ALCOHOL), mixture

· **Maritime transport IMDG:**



- **IMDG Class:** 3
- **UN Number:** 1170
- **Label:** 3
- **Packaging group:** II
- **EMS Number:** F-E,S-D
- **Marine pollutant:** No

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· **Propper shipping name:** ETHANOL (ETHYL ALCOHOL), mixture

· **Air transport ICAO-TI and IATA-DGR:**



· **ICAO/IATA Class:** 3
 · **UN/ID Number:** 1170
 · **Label** 3
 · **Packaging group:** II
 · **Propper shipping name:** ETHANOL, mixture

· **UN "Model Regulation":** UN1170; ETHANOL (ETHYL ALCOHOL), mixture; 3; II

15 Regulatory information

· **Sara**

· **Section 355 (extremely hazardous substances):**

None of the ingredient is listed.

· **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

All ingredients are listed.

· **Proposition 65**

· **Chemicals known to cause cancer:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

64-17-5 | ethanol

· **Carcinogeny categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

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· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

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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: 5**· **Relevant phrases**

H225 Highly flammable liquid and vapour.

H227 Combustible liquid.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

USA