

Printing date 10/02/2008

Reviewed on 10/01/2008




**1 Identification of substance**

- **Product details**
- **Trade name:** CLEARFIL SA CEMENT; PASTE A & B
- **Article number:** US142
- **Application of the substance / the preparation** Resin-based dental adhesive cement
- **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
- **Information department:** Supplier

**2 Composition/Data on components**

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

· **Dangerous components:**

1565-94-2	bisphenol A diglycidylmethacrylate	Warning:  3.2/2, 3.3/2A	<8%
7681-49-4	sodium fluoride	Danger:  3.1.O/3, 3.2/2, 3.3/2A	<5%
109-16-0	triethylene glycol dimethacrylate	Warning:  3.2/2, 3.3/2A, 3.8/3	<3%

· **Other ingredients:**

10-Methacryloyloxydecyl dihydrogen phosphate  
Hydrophobic aromatic dimethacrylate  
Hydrophobic aliphatic dimethacrylate  
Silanated barium glass filler  
Silanated colloidal silica  
dl-Camphorquinone  
Initiators  
Accelerators  
Catalysts  
Pigments  
Others

**3 Hazards identification**· **Hazard description:**

Harmful

· **Information pertaining to particular dangers for man and environment:**

The product has to be labelled due to the calculation procedure of international guidelines.  
Harmful if swallowed.  
Contact with acids liberates toxic gas.

· **Classification system:**

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

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· **NFPA ratings (scale 0 - 4)**

Health = 2

Fire = 0

Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**

Health = 2

Fire = 0

Reactivity = 0

· **GHS label elements****Warning**

3.1/4 - Harmful if swallowed.

· **Prevention:**

Wash thoroughly after handling.

Do not eat, drink or smoke when using this product.

· **Response:**

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

Rinse mouth.

· **Disposal:**

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

**4 First aid measures**· **General information:**

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

· **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. Then consult a doctor.· **After swallowing:** Immediately call a doctor.**5 Fire fighting measures**· **Suitable extinguishing agents:**CO<sub>2</sub>, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.· **Protective equipment:**

Wear fully protective suit.

Mouth respiratory protective device.

**6 Accidental release measures**· **Person-related safety precautions:** Mount respiratory protective device.· **Measures for environmental protection:** Do not allow to enter sewers/ surface or ground water.· **Measures for cleaning/collecting:** Dispose contaminated material as waste according to item 13.**7 Handling and storage**· **Handling:**· **Information for safe handling:** Prevent formation of dust.· **Information about protection against explosions and fires:** No special measures required.· **Storage:**· **Requirements to be met by storerooms and receptacles:** Store in a refrigerator (2-8°C).

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· **Information about storage in one common storage facility:**

Store away from oxidizing agents.

Store away from reducing agents.

Do not store together with acids.

· **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 and 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:****7681-49-4 sodium fluoride**PEL 2.5 mg/m<sup>3</sup>

as F

REL 2.5 mg/m<sup>3</sup>

as F

TLV 2.5 mg/m<sup>3</sup>

as F, BEI

· **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:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

· **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:** Not required.**9 Physical and chemical properties**· **General Information**

<b>Form:</b>	Pasty
<b>Color:</b>	Colored
<b>Odor:</b>	Odorless

· **Change in condition**

<b>Melting point/Melting range:</b>	1012 °C (sodium fluoride)
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· Boiling point/Boiling range:	1704 °C (sodium fluoride)
· Flash point:	Not applicable.
· Ignition temperature:	Not applicable
· Danger of explosion:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not applicable
Upper:	Not applicable
· Vapor pressure:	Not applicable
· Density:	1.8 g/cm <sup>3</sup>
· Vapour density	Not applicable
· Solubility in / Miscibility with Water:	Insoluble.
· pH-value:	Not applicable
· Segregation coefficient (n-octanol/water):	Not applicable

## 10 Stability and reactivity

- **Thermal decomposition / conditions to be avoided:**  
No decomposition if used and stored according to specifications.
- **Dangerous reactions** No dangerous reactions known.
- **Dangerous products of decomposition:** Carbon monoxide and carbon dioxide

## 11 Toxicological information

- **Acute toxicity:**

- **LD/LC50 values that are relevant for classification:**

**7681-49-4 sodium fluoride**

Oral	LD50	44 mg/kg (mouse)
		52 mg/kg (rat)

- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**  
The product shows the following dangers according to internally approved calculation methods for preparations:  
Harmful

## 12 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.

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**13 Disposal considerations**

- **Product:**
- **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.

**14 Transport information**

- **DOT regulations:**
- **Hazard class:** -
- **Land transport ADR/RID (cross-border):**
- **ADR/RID class:** -
- **Maritime transport IMDG:**
- **IMDG Class:** -
- **Marine pollutant:** No
- **Air transport ICAO-TI and IATA-DGR:**
- **ICAO/IATA Class:** -
- **UN "Model Regulation":** -

**15 Regulations**

- **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:**

None of the ingredients is listed.

**· Cancerogenity categories****· EPA (Environmental Protection Agency)**

None of the ingredients is listed.

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

None of the ingredients is listed.

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· **NTP (National Toxicology Program)**

None of the ingredients is listed.

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

None of the ingredients is listed.

· **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.

· **Product related hazard informations:**

The product has been classified and marked in accordance with directives on hazardous materials.

· **Hazard symbols:**

Harmful

· **Hazard-determining components of labelling:**sodium fluoride  
bisphenol A diglycidylmethacrylate  
triethylene glycol dimethacrylate· **Risk phrases:**Harmful if swallowed.  
Contact with acids liberates toxic gas.· **Safety phrases:**Do not breathe dust.  
In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.  
After contact with skin, wash immediately with plenty of soap and water.  
Wear suitable protective clothing and gloves.  
In case of accident or if you feel unwell, seek medical advice immediately.  
This material and its container must be disposed of as hazardous waste.**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**· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises Dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)  
RID: Règlement internationale concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)  
IMDG: International Maritime Code for Dangerous Goods  
DOT: US Department of Transportation  
IATA: International Air Transport Association  
IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)  
ICAO: International Civil Aviation Organization  
ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)  
GHS: Globally Harmonized System of Classification and Labelling of Chemicals  
ACGIH: American Conference of Governmental Industrial Hygienists  
NFPA: National Fire Protection Association (USA)  
HMIS: Hazardous Materials Identification System (USA)  
GefStoffV: Gefahrstoffverordnung (Ordinance on Hazardous Substances, Germany)  
LC50: Lethal concentration, 50 percent  
LD50: Lethal dose, 50 percent