


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

- **Date of issue:** 20.12.2018
- **1.1 Product identifier**
- **Trade name:** PANAVIA SA Cement Universal
- **Article number:** 231
- **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 35835  
Fax:+49 (0)69 305 98 35835  
E-mail: dental@kuraray.de
- **Further information obtainable from:** Manufacturer
- **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.  
Skin Sens. 1 H317 May cause an allergic skin reaction.
- **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:**  
bisphenol A diglycidylmethacrylate  
triethylene glycol dimethacrylate  
sodium fluoride  
2-hydroxyethyl methacrylate
- **Hazard statements**  
H315 Causes skin irritation.  
H319 Causes serious eye irritation.

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H317 May cause an allergic skin reaction.

**Precautionary statements**

- P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
- P264 Wash hands thoroughly after handling.
- P272 Contaminated work clothing should not be allowed out of the workplace.
- P280 Wear protective gloves / eye protection / face protection.
- P302+P352 IF ON SKIN: Wash with plenty of water.
- P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P362+P364 Take off contaminated clothing and wash it before reuse.
- P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
- P337+P313 If eye irritation persists: Get medical advice/attention.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

**Additional Information**

EUH032 Contact with acids liberates very toxic gas.

**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	1-10%
CAS: 109-16-0 EINECS: 203-652-6	triethylene glycol dimethacrylate ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	1-10%
CAS: 868-77-9 EINECS: 212-782-2	2-hydroxyethyl methacrylate ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	1-3%
CAS: 7681-49-4 EINECS: 231-667-8	sodium fluoride ⚠ Acute Tox. 3, H301; ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319	<1%

**Other ingredients:**

- Silanated barium glass filler
- Silanated colloidal silica
- Aluminum oxide filler
- 10-Methacryloyloxydecyl dihydrogen phosphate
- Hydrophobic aromatic dimethacrylate
- Silane coupling agent
- dl-Camphorquinone
- Peroxide
- Accelerators
- Catalysts
- Pigments

· **Additional information:** EUH032: Contact with acids liberates very toxic gas.(sodium fluoride)**SECTION 4: First aid measures****4.1 Description of first aid measures****General information:**

- Avoid contact with eyes.
- Avoid contact with skin.

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- **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.  
If skin irritation continues, consult a doctor.
- **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:**  
CO<sub>2</sub>, 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 fully protective suit.

### 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 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.

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· **8.1 Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**

**7681-49-4 sodium fluoride**

WEL	Long-term value: 2.5 mg/m <sup>3</sup> as F
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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.

· **Respiratory protection:** Not required.

· **Protection of hands:**

Neoprene 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:** Goggles recommended during refilling

## SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· **Form:** Pasty

· **Colour:** Coloured

· **Odour:** Odourless

· **Odour threshold:** Not determined

· **pH-value:** Not determined

· **Change in condition**

· **Melting point/freezing point:** Not determined

· **Initial boiling point and boiling range:** Not determined

· **Flash point:** Not determined

· **Flammability (solid, gas):** Not determined

· **Ignition temperature:** Not determined

· **Decomposition temperature:** Not determined

· **Explosive properties:** Product does not present an explosion hazard.

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· <b>Explosion limits:</b>	
<b>Lower:</b>	Not determined
<b>Upper:</b>	Not determined
· <b>Oxidising properties</b>	Not determined
· <b>Vapour pressure:</b>	Not determined
· <b>Density:</b>	1.8-1.9g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined
· <b>Vapour density</b>	Not determined
· <b>Evaporation rate</b>	Not determined
· <b>Solubility in / Miscibility with water:</b>	Insoluble.
· <b>Partition coefficient: n-octanol/water:</b>	Not determined
· <b>Viscosity:</b>	Not determined
· <b>Dynamic:</b>	Not determined
· <b>Kinematic:</b>	Not determined
· <b>9.2 Other information</b>	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	4,680 mg/kg (guinea pig)
		3,275 mg/kg (mouse)
		5,050 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.
- **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.

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· **Aspiration hazard** Based on available data, the classification criteria are not met.

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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.

### SECTION 14: Transport information

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|--|-----------------|
| · <b>14.1 UN-Number</b>  |                 |
| · <b>ADR, ADN, IMDG, IATA</b>  | Void            |
| · <b>14.2 UN proper shipping name</b>  |                 |
| · <b>ADR, ADN, IMDG, IATA</b>  | Void            |
| · <b>14.3 Transport hazard class(es)</b>   |                 |
| · <b>ADR, ADN, IMDG, IATA</b>  |                 |
| · <b>Class</b>   | Void            |
| · <b>14.4 Packing group</b>  |                 |
| · <b>ADR, IMDG, IATA</b>   | Void            |
| · <b>14.5 Environmental hazards:</b>   |                 |
| · <b>Marine pollutant:</b>   | No              |
| · <b>14.6 Special precautions for user</b>                                       | Not applicable. |
| · <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b> | Not applicable. |
| · <b>UN "Model Regulation":</b>  | Void            |

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**  
No further relevant information available.

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- **Directive 94/33/EC:** Care should be taken when people under 18 handle this product.
- **Directive 94/85/EEC:** No further relevant information available.
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of 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:**

Acute Tox. 3: Acute toxicity – Category 3  
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  
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3