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.
· 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.
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.

<table>
<thead>
<tr>
<th>CAS</th>
<th>Description</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>1565-94-2</td>
<td>bisphenol A diglycidylmethacrylate</td>
<td>1-10%</td>
</tr>
<tr>
<td>216-367-7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>109-16-0</td>
<td>triethylene glycol dimethacrylate</td>
<td>1-10%</td>
</tr>
<tr>
<td>203-652-6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>868-77-9</td>
<td>2-hydroxyethyl methacrylate</td>
<td>1-3%</td>
</tr>
<tr>
<td>212-782-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7681-49-4</td>
<td>sodium fluoride</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>231-667-8</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **Other ingredients:**
  - Silanated barium glass filler
  - Silanated colloidal silica
  - Aluminum oxide filler
  - 10-Methacyryloyloxydecyl 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.
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 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.

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:
  - 7681-49-4 sodium fluoride
    - WEL Long-term value: 2.5 mg/m³ as F

- 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.
Trade name: PANAVIA SA Cement Universal

- Explosion limits:
  - Lower: Not determined
  - Upper: Not determined
- Oxidising properties: Not determined
- Vapour pressure: Not determined
- Density: 1.8-1.9g/cm³
- Relative density: Not determined
- Vapour density: Not determined
- Evaporation rate: Not determined
- Solubility in / Miscibility with water: Insoluble.
- Partition coefficient: n-octanol/water: Not determined
- Viscosity:
  - Dynamic: Not determined
  - Kinematic: 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:

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Oral LD50</th>
<th>Mouse LC50</th>
<th>Rat LC50</th>
</tr>
</thead>
<tbody>
<tr>
<td>868-77-9 2-hydroxyethyl methacrylate</td>
<td>4,680 mg/kg (guinea pig)</td>
<td>3,275 mg/kg (mouse)</td>
<td>5,050 mg/kg (rat)</td>
</tr>
</tbody>
</table>

- 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 (cancer, 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.
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

- **14.1 UN-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**: Void
  - **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 Transport in bulk according to Annex II of Marpol and the IBC Code**
  - Not applicable.

- **UN "Model Regulation"**: Void

SECTION 15: Regulatory information

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