


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.

(Contd. on page 2)

Trade name: PANAVIA SA Cement Universal

(Contd. of page 1)

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.

(Contd. on page 3)

Trade name: PANAVIA SA Cement Universal

(Contd. of page 2)

- **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:**
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.
- **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.

(Contd. on page 4)

Trade name: PANAVIA SA Cement Universal

(Contd. of page 3)

· **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 ³ 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.

(Contd. on page 5)

Trade name: PANAVIA SA Cement Universal

(Contd. of page 4)

· Explosion limits:	
Lower:	Not determined
Upper:	Not determined
· Oxidising properties	Not determined
· Vapour pressure:	Not determined
· Density:	1.8-1.9g/cm ³
· 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:	Not determined
· 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:	
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.

(Contd. on page 6)

Trade name: PANAVIA SA Cement Universal

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

(Contd. of page 5)

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 | |
| · 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.

(Contd. on page 7)

Trade name: PANAVIA SA Cement Universal

(Contd. of page 6)

- **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