


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

- **1.1 Product identifier**
- **Trade name:** PANAVIA Veneer LC
- **Article number:** 236
- **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** Dental materials
- **1.3 Details of the supplier of the safety data sheet**
- **Supplier :**
Kuraray Europe GmbH
Philipp-Reis-Str. 4,
65795 Hattersheim am Main
Germany
Phone: +49 (0)69 305 35 835
E-mail: dental.eu@kuraray.com
- **Further information obtainable from:** Supplier
- **1.4 Emergency telephone number:**
[United Kingdom] Only for NHS and other healthcare professionals; UK National Poisons Information Service (NPIS): +44 (0)344 892 0111 Ireland NPIC: +353 (0)1 809 2566
For members of Public; NHS 111 in England: 111, NHS 24 in Scotland: 111, NHS Direct in Wales: 111 or 0845 4647, Ireland NPIC: +353 (0)1 809 2166(8 am to 10 pm)
3E Company; (UK) 0 800 680 0425 (GB) +44 20 35147487 (AU) +61 2 80363166 *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 Sens. 1 H317 May cause an allergic skin reaction.
 - **Additional information**
Medical devices as defined in Regulation (EU) 2017/745 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 (GB 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 GB CLP regulation.
 - **Hazard pictograms**
- 

GHS07
- **Signal word** Warning
 - **Hazard-determining components of labelling:**
Urethane dimethacrylate
Triethyleneglycol dimethacrylate
phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide
 - **Hazard statements**
H317 May cause an allergic skin reaction.
 - **Precautionary statements**
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves.
P302+P352 IF ON SKIN: Wash with plenty of water.

(Contd. on page 2)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 09.05.2024

Version number 3 (replaces version 2)

Revision date: 09.05.2024

Trade name: PANAVIA Veneer LC

(Contd. of page 1)

- P362+P364 Take off contaminated clothing and wash it before reuse.
- P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
- P321 Specific treatment (see on this label).
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.2 Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 72869-86-4 EINECS: 276-957-5	Urethane dimethacrylate ⚠ Skin Sens. 1B, H317	10 - 25%
CAS: 109-16-0 EINECS: 203-652-6	Triethyleneglycol dimethacrylate ⚠ Skin Sens. 1B, H317	5 -10%
CAS: 162881-26-7 ELINCS: 423-340-5	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide ⚠ Skin Sens. 1A, H317; Aquatic Chronic 4, H413	< 0.1%

- **Other ingredients:**
Silanated spherical silica filler
Ytterbium trifluoride
Hydrophilic amide monomer
Initiator
Accelerator
dl-Camphorquinone
Pigments
- **Additional information:** Silicon oxide; Nanoform, Silanated amorphous silica, particle size 1 - 100 nm

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:**
Immediately remove any clothing soiled by the product.
Avoid contact with eyes.
Avoid contact with skin.
- **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.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **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.

GB

(Contd. on page 3)

Trade name: PANAVIA Veneer LC

(Contd. of page 2)

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.
 Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

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:**
 Dispose contaminated material as waste according to section 13.
 Ensure adequate ventilation.
 Contain spill, then place in a suitable container. Minimize dust generation. Do not flush to sewer or allow to enter waterways.
 Vacuum or sweep material and place in a disposal container. Provide ventilation.
 Use appropriate Personal Protective Equipment (PPE).
- **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**
 Ensure good ventilation/exhaustion at the workplace.
 Avoid contact with skin and eyes. Do not swallow. Avoid generating dust. Do not breathe dust/fume/gas/mist/vapors/spray.
- **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 refrigerator (2-8°C).
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
 Keep container tightly sealed.
 Protect from heat and direct sunlight.
 Store in cool, dry conditions in well sealed receptacles.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

· **8.1 Control parameters**

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

13760-80-0 ytterbium trifluoride

WEL (Great Britain)	Long-term value: 2.5 mg/m ³ as F
IOELV (EU)	Long-term value: 2.5 mg/m ³ as F

(Contd. on page 4)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 09.05.2024

Version number 3 (replaces version 2)

Revision date: 09.05.2024

Trade name: PANA VIA Veneer LC

(Contd. of page 3)

- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Appropriate engineering controls** No further data; see section 7.
- **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.
- **Respiratory protection:**
 In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
 Suitable respiratory protective device recommended.
- **Hand protection**



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 trough time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye/face protection** Safety glasses

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **Physical state** Solid
- **Colour:** Colored
- **Odour:** Odourless
- **Melting point/freezing point:** Not determined.
- **Boiling point or initial boiling point and boiling range** Not determined.
- **Flammability** Not determined.
- **Lower and upper explosion limit**
- **Lower:** Not applicable.
- **Upper:** Not applicable.
- **Flash point:** Not applicable
- **Auto-ignition temperature:** Not applicable.
- **Decomposition temperature:** Not applicable.
- **pH** Not determined.
- **Kinematic viscosity** Not applicable.
- **Solubility**
- **water:** Insoluble.
- **Partition coefficient n-octanol/water (log value)** Not applicable.
- **Vapour pressure:** Not determined.
- **Density at 20 °C:** 1.8 g/cm³

(Contd. on page 5)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 09.05.2024

Version number 3 (replaces version 2)

Revision date: 09.05.2024

Trade name: PANAVIA Veneer LC

(Contd. of page 4)

· Relative vapour density	Not applicable.
· Particle characteristics	See section 3.
· 9.2 Other information	
· Information with regard to physical hazard classes	
· Explosives	Product does not present an explosion hazard.
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

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 hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.

· **LD/LC50 values relevant for classification:**

72869-86-4 Urethane dimethacrylate

Oral	LD50	2,000 mg/kg (rat)
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- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** May cause an allergic skin reaction.
- **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.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

(Contd. on page 6)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 09.05.2024

Version number 3 (replaces version 2)

Revision date: 09.05.2024

Trade name: PANAVIA Veneer LC

(Contd. of page 5)

· **11.2 Information on other hazards**

· **Endocrine disrupting properties**

None of the ingredients is listed.

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.

· **12.5 Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **12.6 Endocrine disrupting properties** For information on endocrine disrupting properties see section 11.

· **12.7 Other adverse effects**

· **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.

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.

Dispose of packaging according to regulations on the disposal of packagings.

Waste Framework Directive (Directive 2008/98/EC on waste)

O-ring used at the top of the plunger in the syringe contains 0.1% or more of SVHC substance.

Octamethylcyclotetrasiloxane (D4) (CAS 556-67-2)

SCIP number: c7edd175-240e-448c-b5da-ed61029da991

The SCIP number shall be communicated down to waste operators of the product.

For more information about the directive, visit ECHA website: <https://echa.europa.eu/understanding-wfd>

SECTION 14: Transport information

· **14.1 UN number or ID number**

· **ADR, ADN, IMDG, IATA**

Void

· **14.2 UN proper shipping name**

· **ADR, ADN, IMDG, IATA**

Void

· **14.3 Transport hazard class(es)**

· **ADR, IMDG, IATA**

· **Class**

Void

· **14.4 Packing group**

· **ADR, ADN, IMDG, IATA**

Void

(Contd. on page 7)

Printing date 09.05.2024

Version number 3 (replaces version 2)

Revision date: 09.05.2024

Trade name: PANAVIA Veneer LC

(Contd. of page 6)

- | | |
|---|-----------------|
| · 14.5 Environmental hazards: | |
| · Marine pollutant: | No |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Maritime transport in bulk according to IMO instruments | Not applicable. |
| · UN "Model Regulation": | Void |

SECTION 15: Regulatory information

· 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

· Regulated explosives precursors

None of the ingredients is listed.

· Regulated poisons

None of the ingredients is listed.

· Reportable explosives precursors

None of the ingredients is listed.

· Reportable poisons

None of the ingredients is listed.

· **Directive 94/33/EC:** Care should be taken when people under 18 handle this product.

· **Directive 94/85/EEC:** No further relevant information available.

· **Named dangerous substances - ANNEX I** None of the ingredient is listed.

· Regulation (EU) No 649/2012

None of the ingredients is listed.

· Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

· Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

None of the ingredients is listed.

· Regulation (EC) No 1005/2009 on substances that deplete the ozone layer – ANNEX I (Ozone-depleting potential)

None of the ingredients is listed.

· Waste Framework Directive (Directive 2008/98/EC on waste)

O-ring used at the top of the plunger in the syringe contains 0.1% or more of SVHC substance.

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· **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.

· Relevant phrases

H317 May cause an allergic skin reaction.

H413 May cause long lasting harmful effects to aquatic life.

· Abbreviations and acronyms:

ELINCS: European List of Notified Chemical Substances

(Contd. on page 8)

Safety data sheet
according to 1907/2006/EC, Article 31

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Skin Sens. 1: Skin sensitisation – Category 1

Skin Sens. 1A: Skin sensitisation – Category 1A

Skin Sens. 1B: Skin sensitisation – Category 1B

Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4

· *** Data compared to the previous version altered.**

(Contd. of page 7)

GB