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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 Esthetic Adhesive Resin Cement System

· 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:

(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.

· 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 statements

H315 Causes skin irritation.

H319 Causes serious eye irritation.

· Precautionary statements

P264 Wash thoroughly after handling.

P280 Wear protective gloves / eye protection / face protection.

P302+P352 IF ON SKIN: Wash with plenty of water. P321 Specific treatment (see on this label).

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

P332+P313 If skin irritation occurs: Get medical advice/attention.

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P362+P364 Take off contaminated clothing and wash it before reuse. P337+P313 If eye irritation persists: Get medical advice/attention.

- · Labelling of packages where the contents do not exceed 125 ml
- · Precautionary statements

EUH208: Contains phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide. May produce an allergic reaction.

- · 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: | | | | |
|-------------------------|-------------------|--|--------|--|
| | | | 10-25% | |
| | EINECS: 276-957-5 | ♦ Skin Irrit. 2, H315; Eye Irrit. 2, H319 | | |
| | | Triethyleneglycol dimethacrylate | 5-10% | |
| | EINECS: 203-652-6 | ♦ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335 | | |
| | CAS: 162881-26-7 | phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide | <0.1% | |
| | ELINCS: 423-340-5 | ♦ Skin Sens. 1A, H317; Aquatic Chronic 4, H413 | | |

· Other ingredients:

Silanated spherical silica filler

Ytterbium trifluoride

Hydrophilic aliphatic dimethacrylate

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
- · After inhalation: Supply fresh air; consult doctor in case of complaints.
- · After skin contact: Immediately wash with water and soap and rinse thoroughly.
- · After eve 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.

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- · 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:

Pick up mechanically. Ensure adequate ventilation.

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 refrigerator (2-8°C).
- Information about storage in one common storage facility: Not required.
- · 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

- · 8.1 Control parameters
- Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

- · Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures: Wash hands before breaks and at the end of work.
- · Respiratory protection: Not required.
- · 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.

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· 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



Tightly sealed goggles

| SECTION 9: Physical and chemical p | roperties |
|---|-----------|
|---|-----------|

· 9.1 Information on basic physical and chemical properties

· General Information

· Physical state · Colour: Coloured Odourless · Odour: Not determined · Melting point/freezing point:

· Boiling point or initial boiling point and boiling

range Not determined · Flammability Not determined

· Lower and upper explosion limit

Not determined · Lower: · Upper: Not determined · Flash point: Not determined Not determined · Auto-ignition temperature: · Decomposition temperature: Not determined ·pH Not determined · Viscosity: Not determined · Kinematic viscosity Not applicable.

·Solubility

Insoluble. · water: · Partition coefficient n-octanol/water (log value) Not determined. Not determined. · Vapour pressure:

· Density and/or relative density

1.8 g/cm³ · Density: Not determined · Relative density Not determined · Relative vapour density · Particle characteristics See item 3.

· 9.2 Other information

· Appearance:

· Form: **Pasty**

· Important information on protection of health and

environment, and on safety.

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

· Change in condition

· Softening point/range

· Oxidising properties Not determined. · Evaporation rate Not determined

· Oxidising gases Void · Gases under pressure Void · Flammable liquids Void · Flammable solids Void · Self-reactive substances and mixtures Void · Pyrophoric liquids Void

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| · 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.
- · Skin corrosion/irritation Causes skin irriation.
- · Serious eye damage/irritation Causes serious eye irritation.
- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · 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.
- · 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

The product does not contain substances with endocrine disrupting properties.

· 12.7 Other adverse effects No further relevant information available.

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- · Additional ecological information:
- · General notes:

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.

| SECTION 14: Transport information | ion | |
|--|-----------------------------|--|
| · 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, 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 Maritime transport in bulk according instruments | g to IMO Not applicable. | |
| · UN "Model Regulation": | Void | |

SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- Directive 94/33/EC: Care should be taken when people under 18 handle this product.
- · Directive 94/85/EEC: No further relevant information available.
- · Chemical safety assessment
- · Named dangerous substances ANNEX I None of the ingredient is listed.
- · Regulation (EU) No 649/2012
- · 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.

· 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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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

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H413 May cause long lasting harmful effects to aquatic life.

· Abbreviations and acronyms:

ELINCS: European List of Notified Chemical Substances

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

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

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

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

* * Data compared to the previous version altered.

GB