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

1.1 Product identifier
- Trade name: VENUS Pearl

1.2 Relevant identified uses of the substance or mixture and uses advised against
- Application of the substance / the mixture: Dental filling material

1.3 Details of the supplier of the safety data sheet
- Manufacturer/Supplier: Kulzer GmbH
  Leipziger Straße 2, 63450 Hanau (Germany)
  Tel.: +49 (0)800 4372522
- Informing department: E-Mail: msds@kulzer-dental.com

1.4 Emergency telephone number:
- Emergency CONTACT (24-Hour-Number): +49 (0)6132-84463

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.

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](image)

- Signal word: Warning

- Hazard-determining components of labelling:
  - 2-Propenoic acid, (octahydro-4,7-methano-1H-indene-5-diy)bis(methyleneiminocarbonyloxy-2,1-ethanediyl) ester
  - triethylen glycol dimethacrylate

- Hazard statements
  - H317: May cause an allergic skin reaction.

- Precautionary statements
  - P261: Avoid breathing dust/fume/gas/mist/vapours/spray.
  - P280: Wear protective gloves/protective clothing/eye protection/face protection.
  - P321: Specific treatment (see on this label).
  - P363: Wash contaminated clothing before reuse.
  - P333+P313: If skin irritation or rash occurs: Get medical advice/attention.
  - P302+P352: IF ON SKIN: Wash with plenty of water.

2.3 Other hazards -
- Results of PBT and vPvB assessment
  - PBT: Not applicable.
Trade name: VENUS Pearl

vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures

Description:

- Dangerous components:

<table>
<thead>
<tr>
<th>CAS</th>
<th>Description</th>
<th>Skin Sens.</th>
<th>Aquatic Chronic</th>
</tr>
</thead>
<tbody>
<tr>
<td>861437-11-8</td>
<td>2-Propenoic acid, (octahydro-4,7-methano-1H-indene-5-diyldi(methyleneiminocarbonyloxy-2,1-ethanediyl) ester</td>
<td>1, H317</td>
<td>3, H412</td>
</tr>
<tr>
<td>109-16-0</td>
<td>triethylen glycol dimethacrylate</td>
<td>1B, H317</td>
<td></td>
</tr>
</tbody>
</table>

Additional information

For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

- After inhalation: Supply fresh air; consult doctor in case of symptoms.
- After skin contact: Instantly 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. Then consult doctor.
- After swallowing: Rinse out mouth and then drink plenty of water. In case of persistent symptoms 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: Use fire fighting measures that suit the environment. CO2, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.

5.2 Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

5.3 Advice for firefighters

- Protective equipment: No special measures required.
- Additional information: -

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

(Contd. on page 3)
6.2 Environmental precautions:
Do not allow to enter drainage system, surface or ground water.
Do not allow to enter the ground/soil.

6.3 Methods and material for containment and cleaning up:
Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).
Dispose of the material collected according to regulations.

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 information on disposal.

SECTION 7: Handling and storage

7.1 Precautions for safe handling
Ensure good ventilation/exhaustion at the workplace.

Information about protection against explosions and fires: No special measures required.

7.2 Conditions for safe storage, including any incompatibilities

Storage
Requirements to be met by storerooms and containers: No special requirements.
Information about storage in one common storage facility: Not required.
Further information about storage conditions: None.

7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters
Components with critical 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.

DNELs
109-16-0 triethylen glycol dimethacrylate
Dermal worker industr., l.te., syst. 13.9 mg/Kg/d (nd)
Inhalative worker industr., l.te., syst. 48.5 mg/m3 (nd)

PNECs
109-16-0 triethylen glycol dimethacrylate

<table>
<thead>
<tr>
<th>Environment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>marine water</td>
<td>0.0164 mg/l (nd)</td>
</tr>
<tr>
<td>sedim., dw, fre.wat.</td>
<td>1.85 mg/Kg (nd)</td>
</tr>
<tr>
<td>sedim., dw, mar.wat.</td>
<td>0.185 mg/Kg (nd)</td>
</tr>
<tr>
<td>soil, dw</td>
<td>0.274 mg/Kg (nd)</td>
</tr>
</tbody>
</table>

Additional information: The lists that were valid during the compilation were used as basis.

8.2 Exposure controls
Personal protective equipment
General protective and hygienic measures
Instantly remove any soiled and impregnated garments.
Wash hands during breaks and at the end of the work.
• Breathing equipment: Not required.

• Protection of hands:
If skin contact cannot be avoided, protective gloves are recommended to avoid possible sensitization.
Check protective gloves prior to each use for their proper condition.

• 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.

• For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:
  Butyl rubber, BR
  Nitrile rubber, NBR

• Eye protection: not absolutely necessary

• Body protection: Light weight protective clothing

SECTION 9: Physical and chemical properties

• 9.1 Information on basic physical and chemical properties

• General Information

• Appearance:
  - Form: Pasty
  - Colour: Different according to colour
  - Smell: Odourless
  - Odour threshold: Not determined.

• pH-value: Not determined.

• Change in condition
  - Melting point/Melting range: Not determined
  - Boiling point/Boiling range: > 250 °C

• Flash point: > 165 °C

• Inflammability (solid, gaseous) Not applicable.

• Ignition temperature:
  - Decomposition temperature: Not determined.

• Self-inflammability: Product is not selfigniting.

• Danger of explosion: Product is not explosive.

• Critical values for explosion:
  - Lower: Not determined.
  - Upper: Not determined.
**Safety data sheet**
according to 1907/2006/EC, Article 31

**Trade name:** VENUS Pearl

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam pressure</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Density at 20 °C</td>
<td>2.1 g/cm³</td>
</tr>
<tr>
<td>Relative density</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Vapour density</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Solubility in / Miscibility with</td>
<td>Water: Not miscible or difficult to mix</td>
</tr>
<tr>
<td>Partition coefficient (n-octanol/water)</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Viscosity dynamic</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Viscosity kinematic</td>
<td>Not determined.</td>
</tr>
</tbody>
</table>

**SECTION 10: Stability and reactivity**

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
  - Conditions to be avoided: No decomposition if used and stored 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**: None
  - Additional information: -

**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 that are relevant for classification:
      - **861437-11-8 Propenioic acid, (octahydro-4,7-methano-1H-indene-5-diyl) bis(methyleneiminocarbonyloxy-2,1-ethanediyl) ester**
        - Oral LD50 >2000 mg/kg (rat)
      - **41137-60-4 diurethandimethacrylate**
        - Oral LD50 >5000 mg/kg (rat)
      - **109-16-0 triethylen glycol dimethacrylate**
        - Oral LD50 > 5000 mg/kg (rat)
        - Dermal LD50 > 2000 mg/kg (mouse)
  - Primary irritant effect:
    - 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.

(Contd. on page 6)
SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity:

861437-11-8 Propenoic acid, (octahydro-4,7-methano-1H-indene-5-diyld) bis(methyleneiminocarbonyloxy-2,1-ethanediyl) ester

EC50/48h 24.9 mg/l (daphnia)
109-16-0 triethylen glycol dimethacrylate
EC50/72h > 100 mg/l (algae)

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: Avoid transfer into the environment.

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
Small quantities can be polymerized by light and the cured solid material can be disposed of with the regular garbage. Larger quantities must be disposed of following the regulations of the local authorities.

Uncleaned packagings:
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
Trade name: **VENUS Pearl**

<table>
<thead>
<tr>
<th>14.3 Transport hazard class(es)</th>
<th>Void</th>
</tr>
</thead>
<tbody>
<tr>
<td>· ADR, ADN, IMDG, IATA</td>
<td></td>
</tr>
<tr>
<td>· Class</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>14.4 Packing group</th>
<th>Void</th>
</tr>
</thead>
<tbody>
<tr>
<td>· ADR, IMDG, IATA</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>14.5 Environmental hazards:</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>· Marine pollutant:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>14.6 Special precautions for user</th>
<th>Not applicable.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</th>
<th>Not applicable.</th>
</tr>
</thead>
<tbody>
<tr>
<td>· Transport/Additional information:</td>
<td>-</td>
</tr>
<tr>
<td>· UN &quot;Model Regulation&quot;:</td>
<td>Void</td>
</tr>
</tbody>
</table>

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
  - REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

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

### SECTION 16: Other information

These data are based on our present knowledge. However, they 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.
  - H412 Harmful to aquatic life with long lasting effects.

- **Abbreviations and acronyms**:
  - ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
  - IMDG: International Maritime Code for Dangerous Goods
  - IATA: International Air Transport Association
  - GHS: Globally Harmonised System of Classification and Labelling of Chemicals
  - EINECS: European Inventory of Existing Commercial Chemical Substances
  - ELINCS: European List of Notified Chemical Substances
  - CAS: Chemical Abstracts Service (division of the American Chemical Society)
  - DNEL: Derived No-Effect Level (REACH)
  - PNEC: Predicted No-Effect Concentration (REACH)
  - LC50: Lethal concentration, 50 percent
  - LD50: Lethal dose, 50 percent
  - PBT: Persistent, Bioaccumulative and Toxic
  - vPvB: very Persistent and very Bioaccumulative
  - Skin Sens. 1: Skin sensitisation – Category 1
  - Skin Sens. 1B: Skin sensitisation – Category 1B
  - Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

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