1 Identification

· Product identifier
  · Trade name: VENUS Pearl

· Application of the substance / the mixture Dental filling material

· Details of the supplier of the safety data sheet
  · Manufacturer/Supplier: Kulzer GmbH
    Leipziger Straße 2, 63450 Hanau (Germany)  
    Tel.: +49 (0)800 4372522

  · Information department:
    Tel. +1 (800) 431-1785  Fax: +1 (800) 522-1545
    e-mail: customer.servicehkna@kulzer-dental.com

  · Emergency telephone number:
    Emergency CONTACT (24-Hour-Number)
    GBK/Infotrac ID  105860: (domestic) 1 800 535 5053 or international (001) 352 323 3500

2 Hazard(s) identification

· Classification of the substance or mixture
  Skin Sens. 1 H317 May cause an allergic skin reaction.

· Label elements
  · GHS label elements
    The product is classified and labeled according to the Globally Harmonized System (GHS).
    · Hazard pictograms
      GHS07

· Signal word Warning

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

· Hazard statements
  May cause an allergic skin reaction.

· Precautionary statements
  Avoid breathing dust/fume/gas/mist/vapors/spray
  Wear protective gloves.
  Specific treatment (see on this label).
  Wash contaminated clothing before reuse.
  If skin irritation or rash occurs: Get medical advice/attention.
  IF ON SKIN: Wash with plenty of water.
Trade name: VENUS Pearl

Classification system
- NFPA ratings for USA (scale 0-4)
  - Health = 0
  - Fire = 1
  - Reactivity = 0

- HMIS-Ratings (Scale 0-4)
  - Health = 0
  - Fire = 1
  - Reactivity = 0

- Results of PBT and vPvB assessment
  - PBT: Not applicable.
  - vPvB: Not applicable.

3 Composition/information on ingredients
- Chemical characterization: Mixtures
- Description: -

- Dangerous components:
<table>
<thead>
<tr>
<th>CAS Number</th>
<th>Chemical Name</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>861437-11-8</td>
<td>2-Propenoic acid, (octahydro-4,7-methano-1H-indene-5-diyl) bis(methyleneiminocarbonyloxy-2,1-ethanediyl) ester</td>
<td>10-25%</td>
</tr>
<tr>
<td>109-16-0</td>
<td>triethylene glycol dimethacrylate</td>
<td>0-5%</td>
</tr>
</tbody>
</table>

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

4 First-aid measures
- 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.
    If skin irritation continues, consult a doctor.
  - After eye contact
    Rinse opened eye for several minutes under running water. Then consult a doctor.
  - After swallowing
    Rinse out mouth and then drink plenty of water.
    If symptoms persist consult doctor.
  - Information for doctor
    - Most important symptoms and effects, both acute and delayed
      No further relevant information available.
    - Indication of any immediate medical attention and special treatment needed
      No further relevant information available.
5 Fire-fighting measures

- Extinguishing media
  - Suitable extinguishing agents
  - Use fire fighting measures that suit the environment.
  - CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

- Special hazards arising from the substance or mixture
  - Formation of toxic gases is possible during heating or in case of fire.

- Advice for firefighters
  - Protective equipment: No special measures required.
  - Additional information -

6 Accidental release measures

- Personal precautions, protective equipment and emergency procedures
  - Wear protective equipment. Keep unprotected persons away.

- Environmental precautions:
  - Do not allow to enter sewers/surface or ground water.
  - Do not allow to penetrate the ground/soil.

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

- 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.

7 Handling and storage

- Handling
  - Precautions for safe handling: Ensure good ventilation/exhaustion at the workplace.
  - Information about protection against explosions and fires: No special measures required.

- Conditions for safe storage, including any incompatibilities
  - Storage
    - Requirements to be met by storerooms and receptacles: No special requirements.
    - Information about storage in one common storage facility: Not required.
    - Further information about storage conditions: None.
  - Specific end use(s): No further relevant information available.

8 Exposure controls/personal protection

- Control parameters
  - Components 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.
Trade name: **VENUS Pearl**

- **Additional information:** The lists that were valid during the creation were used as basis.

  - **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.
      - **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 through time has to be found out by the manufacturer of the protective gloves and has to be observed.
  - **Eye protection:** Not absolutely necessary.
  - **Body protection:** Light weight protective clothing

**9 Physical and chemical properties**

  - **Information on basic physical and chemical properties**
    - **General Information**
      - **Appearance:**
        - **Form:** Pasty
        - **Color:** Different according to coloring
        - **Odor:** Odorless
        - **Odor threshold:** Not determined.
      - **pH-value:** Not determined.
    - **Change in condition**
      - **Melting point/Melting range:** Undetermined
      - **Boiling point/Boiling range:** > 250 °C (> 482 °F)
    - **Flash point:** > 165 °C (> 329 °F)
    - **Flammability (solid, gaseous):** Not applicable.
  - **Ignition temperature:**
    - **Decomposition temperature:** Not determined.
10 Stability and reactivity

- Reactivity: No further relevant information available.
- Possibility of hazardous reactions: No dangerous reactions known
- Conditions to avoid: No further relevant information available.
- Incompatible materials: No further relevant information available.
- Hazardous decomposition products: none
- Additional information: -

11 Toxicological information

- Information on toxicological effects
- Acute toxicity:
  - LD/LC50 values that are relevant for classification:
    | Chemical | LD50/LC50 |
    |----------|-----------|
    | 861437-11-82 Propenoic acid, (octahydro-4,7-methano-1H-indene-5-diyl) bis(methyleneiminocarbonylox-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:
  - on the skin: No irritant effect.
Trade name: VENUS Pearl

· on the eye: No irritating effect.
· Sensitization: No sensitizing effects known.
· Additional toxicological information:
· Carcinogenic categories

- IARC (International Agency for Research on Cancer)
  None of the ingredients is listed.

- NTP (National Toxicology Program)
  None of the ingredients is listed.

- OSHA-Ca (Occupational Safety & Health Administration)
  None of the ingredients is listed.

12 Ecological information

- Toxicity
  - Aquatic toxicity:

  861437-11-8 2-propenoic acid, (octahydro-4,7-methano-1H-indene-5-diyl) 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)

  - Persistence and degradability No further relevant information available.
  - Behavior in environmental systems:
    - Bioaccumulative potential No further relevant information available.
    - Mobility in soil No further relevant information available.
  - Additional ecological information:
    - General notes: Avoid transfer into the environment.
  - Results of PBT and vPvB assessment
    - PBT: Not applicable.
    - vPvB: Not applicable.
  - Other adverse effects No further relevant information available.

13 Disposal considerations

- 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.
### 14 Transport information

<table>
<thead>
<tr>
<th>· UN-Number</th>
<th>Void</th>
</tr>
</thead>
<tbody>
<tr>
<td>· DOT, ADR, ADN, IMDG, IATA</td>
<td></td>
</tr>
<tr>
<td>· UN proper shipping name</td>
<td>Void</td>
</tr>
<tr>
<td>· DOT, ADR, ADN, IMDG, IATA</td>
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<tr>
<td>· Transport hazard class(es)</td>
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<td>· Environmental hazards:</td>
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<tr>
<td>· Marine pollutant:</td>
<td>No</td>
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<tr>
<td>· Special precautions for user</td>
<td>Not applicable.</td>
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<tr>
<td>· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>· Transport/Additional information:</td>
<td>-</td>
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<tr>
<td>· UN “Model Regulation”:</td>
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### 15 Regulatory information

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<td>· SARA Section 355 (extremely hazardous substances)</td>
</tr>
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<td>· TSCA (Toxic Substances Control Act) Medical devices are exempted from TSCA.</td>
</tr>
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<td>· Cancerogenity categories</td>
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<td>· TLV (Threshold Limit Value established by ACGIH)</td>
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Safety Data Sheet
acc. to OSHA HCS

Trade name: VENUS Pearl

· Hazard statements
  May cause an allergic skin reaction.

· Precautionary statements
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  Wear protective gloves.
  Specific treatment (see on this label).
  Wash contaminated clothing before reuse.
  If skin irritation or rash occurs: Get medical advice/attention.
  IF ON SKIN: Wash with plenty of water.

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

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.

· Date of preparation / last revision 06/03/2017 / 2

· 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
  DOT: US Department of Transportation
  IATA: International Air Transport Association
  ACGIH: American Conference of Governmental Industrial Hygienists
  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)
  HIMS: Hazardous Materials Identification System (USA)
  LC50: Lethal concentration, 50 percent
  LD50: Lethal dose, 50 percent
  PBT: Persistent, Bioaccumulative and Toxic
  vPvB: very Persistent and very Bioaccumulative
  OSHA: Occupational Safety & Health
  TLV: Threshold Limit Value
  PEL: Permissible Exposure Limit
  REL: Recommended Exposure Limit
  Skin Sens. 1: Skin sensisation – Category 1
  Skin Sens. 1B: Skin sensisation – Category 1B

· * Data compared to the previous version altered.