1 Identification

- **Product identifier**
  - **Trade name:** Venus Bulk Fill

- **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)
  - **Information department:**
    Tel.: +49 (0)800 4372522
  - **Emergency telephone 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 Irritation - Category 2** H315 Causes skin irritation.
  - **Eye Irritation - Category 2A** H319 Causes serious eye irritation.

- **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 statements**
  - Causes skin irritation.
  - Causes serious eye irritation.

- **Precautionary statements**
  - Wear protective gloves/protective clothing/eye protection/face protection.
  - Wash thoroughly after handling.
  - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  - Specific treatment (see on this label).
  - IF EYES CONTINUE TO IRRITATE: Get medical advice/attention.
  - IF ON SKIN: Wash with plenty of water.

- **Classification system**
  - **NFPA ratings for USA (scale 0-4)**

  - Health = 1
  - Fire = 1
  - Reactivity = 0

(Contd. on page 2)
Trade name: Venus Bulk Fill

3 Composition/information on ingredients

- Chemical characterization: Mixtures
- Description: -

- Dangerous components:
  - 13760-80-0 ytterbium trifluoride
  - Skin Irritation - Category 2, H315; Eye Irritation - Category 2A, H319;
  - Specific Target Organ Toxicity - Single Exposure - Category 3, H335
  - 10-25% w/w

4 First-aid measures

- Description of first aid measures
  - General information No special measures required.
  - After inhalation Supply fresh air; consult doctor in case of complaints.
  - 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 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
    - CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
    - Use fire fighting measures that suit the environment.
  - Special hazards arising from the substance or mixture No further relevant information available.
  - Advice for firefighters
    - Protective equipment: No special measures required.
  - Additional information -
## 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions**: No special measures required.
- **Methods and material for containment and cleaning up**: Pick up mechanically.
- **Reference to other sections**
  - See Section 13 for disposal information.
  - See Section 8 for information on personal protection equipment.

## 7 Handling and storage

- **Handling**
  - **Precautions for safe handling** No special measures required.
  - **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**: Store in dry conditions. Keep cool, if possible (not above 25 °C).
- **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.
  - **Additional information**: The lists that were valid during the creation were used as basis.
- **Exposure controls**
  - **Personal protective equipment**
    - **General protective and hygienic measures** Wash hands before breaks and at the end of work.
    - **Breathing equipment**: Not required.
    - **Protection of hands**
      - The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
      - Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
      - 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.
Trade name: Venus Bulk Fill

- **Penetration time of glove material**
  The exact breakthrough 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:** Safety glasses

- **Body protection:** Light weight protective clothing

### 9 Physical and chemical properties

- **Information on basic physical and chemical properties**
  **General Information**
  - **Appearance:** Pasty
    - **Form:** Pasty
    - **Color:** White
      - **Yellowish**
    - **Odor:** Odorless
    - **Odor threshold:** Not determined.
  - **pH-value:** Not determined.
  - **Change in condition**
    - **Melting point/Melting range:** undetermined
    - **Boiling point/Boiling range:** undetermined
  - **Flash point:** > 100 °C (> 212 °F)
  - **Flammability (solid, gaseous)** Not applicable.
  - **Ignition temperature:**
  - **Decomposition temperature:** Not determined.
  - **Auto igniting:** Product is not selfigniting.
  - **Danger of explosion:** Product does not present an explosion hazard.
  - **Explosion limits:**
    - **Lower:** Not determined.
    - **Upper:** Not determined.
  - **Vapor pressure:** Not determined.
  - **Density at 20 °C (68 °F):** 1.9 g/cm³ (15.856 lbs/gal)
    - **Relative density:** Not determined.
    - **Vapor density:** Not determined.
    - **Evaporation rate:** Not determined.
  - **Solubility in / Miscibility with**
    - **Water:** Not miscible or difficult to mix
  - **Partition coefficient (n-octanol/water):** Not determined.
**Trade name:** Venus Bulk Fill

**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**: No further relevant information available.

**11 Toxicological information**
- **Information on toxicological effects**
  - **Acute toxicity**:
    - **LD/LC50 values that are relevant for classification**:
      - **56744-60-6 Bisphenol-A-ethoxylat(4)dimethacrylat**
        - 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.
    - **on the eye**: No irritating effect.
    - **Sensitization**: No sensitizing effects known.
  - **Additional toxicological information**:
    The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
    When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

**Carcinogenic categories**
- **IARC (International Agency for Research on Cancer)**
  - 7631-86-9 silicon dioxide, chemically prepared 3
  - Butyl-hydroxy-toluol 3
- **NTP (National Toxicology Program)**
  - None of the ingredients is listed.
12 Ecological information

- Toxicity
  - Aquatic toxicity:
    - 109-16-0 triethylen glycol dimethacrylate
    - EC50/72h > 100 mg/l (algae)
      - Eigene Untersuchung von EVONIK
  - 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: Smaller quantities can be disposed of with household waste.
- Uncleaned packagings:
  - Recommendation: Disposal must be made according to official regulations.

14 Transport information

- UN-Number
  - DOT, TDG, ADN, IMDG, IATA: Void
- UN proper shipping name
  - DOT, TDG, ADN, IMDG, IATA: Void
- Transport hazard class(es)
  - DOT, TDG, ADN, IMDG, IATA
    - Class: Void
- Packing group
  - DOT, TDG, IMDG, IATA: Void
- Environmental hazards:
  - Marine pollutant: No
- Special precautions for user: Not applicable.
- Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: Not applicable.
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15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
  - SARA Section 355 (extremely hazardous substances)
    None of the ingredients is listed.
  - TSCA (Toxic Substances Control Act) Medical devices are exempted from TSCA.
  - GHS label elements
    The product is classified and labeled according to the Globally Harmonized System (GHS).
      - Hazard pictograms
        GHS07
        - Signal word Warning
        - Hazard statements
          Causes skin irritation.
          Causes serious eye irritation.
        - Precautionary statements
          Wear protective gloves/protective clothing/eye protection/face protection.
          Wash thoroughly after handling.
          IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
          Specific treatment (see on this label).
          IF eye irritation persists: 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
  - H315 Causes skin irritation.
  - H319 Causes serious eye irritation.
  - H335 May cause respiratory irritation.
- Date of preparation / last revision 06/03/2017 / 2
- Abbreviations and acronyms:
  - IMDG: International Maritime Code for Dangerous Goods
  - DOT: US Department of Transportation
  - IATA: International Air Transport Association
  - EINECS: European Inventory of Existing Commercial Chemical Substances
  - ELINCS: European List of Notified Chemical Substances
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CAS: Chemical Abstracts Service (division of the American Chemical Society)
NFPA: National Fire Protection Association (USA)
HMIS: 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

* Data compared to the previous version altered.