



**Safety Data Sheet  
acc. to OSHA HCS**

Printing date 06/06/2021

Reviewed on 06/06/2021

## 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)

Tel.: +49 (0)800 4372522

· **Information department:**

Tel. +1 (800) 431-1785 Fax: +1 (800) 522-1545

e-mail: [customer.servicehkna@kulzer-dental.com](mailto:customer.servicehkna@kulzer-dental.com)

· **Emergency telephone number:**

Emergency CONTACT (24-Hour-Number)

ID 105860: (domestic) 1 800 535 5053 or international (001) 352 323 3500

## 2 Hazard(s) identification

· **Classification of the substance or mixture**

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2A H319 Causes serious eye irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction.

Repr. 1B H360 May damage fertility or the unborn child.

· **Label elements**

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**



GHS07 GHS08

· **Signal word** Danger

· **Hazard-determining components of labeling:**

7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahehexadecane-1,16-diyl bismethacrylate

2-ethylhexyl 4-(dimethylamino)benzoate

· **Hazard statements**

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

May damage fertility or the unborn child.

· **Precautionary statements**

Wear protective gloves/protective clothing/eye protection/face protection.

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 skin irritation occurs: Get medical advice/attention.

Take off contaminated clothing.

Store locked up.

(Contd. on page 2)

US



**Safety Data Sheet**  
**acc. to OSHA HCS**

Printing date 06/06/2021

Reviewed on 06/06/2021

**Trade name: Venus Bulk Fill**

(Contd. of page 1)

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



- **HMIS-Ratings (Scale 0-4)**



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

### 3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** -

- **Dangerous components:**

13760-80-0	ytterbium trifluoride Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335	≥10-<20%
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate Skin Sens. 1B, H317	10-25%
21245-02-3	2-ethylhexyl 4-(dimethylamino)benzoate Repr. 1B, H360	≥0.1-<1%

### 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**  
CO<sub>2</sub>, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

(Contd. on page 3)



**Safety Data Sheet  
acc. to OSHA HCS**

Printing date 06/06/2021

Reviewed on 06/06/2021

**Trade name: Venus Bulk Fill**

(Contd. of page 2)

- 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.
    - Not required.
    - **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.
  - recommended

(Contd. on page 4)



**Safety Data Sheet**  
**acc. to OSHA HCS**

Printing date 06/06/2021

Reviewed on 06/06/2021

**Trade name: Venus Bulk Fill**

(Contd. of page 3)

- **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.
- **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:

- **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.

- **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/cm<sup>3</sup> (15.8555 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.

#### · Viscosity:

- **dynamic:** Not determined.

(Contd. on page 5)



**Safety Data Sheet  
acc. to OSHA HCS**

Printing date 06/06/2021

Reviewed on 06/06/2021

**Trade name: Venus Bulk Fill**

(Contd. of page 4)

· **kinematic:** Not determined.

· **Other information** No further relevant information available.

### 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:**

**56744-60-6 Bisphenol-A-ethoxylat(4)dimethacrylat**

Oral LD50 >2000 mg/kg (rat)

**72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate**

Oral LD50 >5000 mg/kg (rat) (OECD 401)

Dermal LD50 >2000 mg/kg (rat) (OECD 402)

**21245-02-3 2-ethylhexyl 4-(dimethylamino)benzoate**

Oral LD50 14900 mg/kg (rat)

- **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

128-37-0 2,6-di-tert-butyl-p-cresol

3

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

(Contd. on page 6)

US



**Safety Data Sheet**  
acc. to OSHA HCS

Printing date 06/06/2021

Reviewed on 06/06/2021

Trade name: **Venus Bulk Fill**

(Contd. of page 5)

· **Reproductive toxicity**

**21245-02-3 2-ethylhexyl 4-(dimethylamino)benzoate**

Oral | NOAEL (Fruchtbarkeit) | 50 mg/kg/d /64 d (rat) (OECD 421)

**12 Ecological information**

· **Toxicity**

· **Aquatic toxicity:**

**72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahectadecane-1,16-diyl bismethacrylate**

EC50/48h >1.2 mg/l (daphnia) (OECD 202)

LC50/96h 10.1 mg/l (fish) (OECD 203)

ErC50 / 72 h >0.68 mg/l (algae) (OECD 201)

NOEC / 72h 0.21 mg/l (algae) (OECD 201)

· **Persistence and degradability**

**72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahectadecane-1,16-diyl bismethacrylate**

biodegradability 22 % /28d (nd) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)

· **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, ADR, ADN, IMDG, IATA Void

· **UN proper shipping name**

· DOT, ADR, ADN, IMDG, IATA Void

· **Transport hazard class(es)**

· DOT, ADR, ADN, IMDG, IATA  
· Class Void

(Contd. on page 7)



**Safety Data Sheet**  
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Trade name: **Venus Bulk Fill**

(Contd. of page 6)

· <b>Packing group</b>	Void
· <b>DOT, ADR, IMDG, IATA</b>	Void
· <b>Environmental hazards:</b>	
· <b>Marine pollutant:</b>	No
· <b>Special precautions for user</b>	Not applicable.
· <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.
· <b>Transport/Additional information:</b>	-
· <b>UN "Model Regulation":</b>	Void

**15 Regulatory information**

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**  
No further relevant information available.

· **Sara**

· **SARA Section 355 (extremely hazardous substances)**

None of the ingredients is listed.

· **SARA Section 313 (specific toxic chemical listings)**

None of the ingredients is listed.

· **Proposition 65**

· **Prop 65 - Chemicals known to cause cancer**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenicity categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value)**

128-37-0 2,6-di-tert-butyl-p-cresol

A4

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **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.

H317 May cause an allergic skin reaction.

(Contd. on page 8)



**Safety Data Sheet  
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Printing date 06/06/2021

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**Trade name: Venus Bulk Fill**

(Contd. of page 7)

*H319 Causes serious eye irritation.*

*H335 May cause respiratory irritation.*

*H360 May damage fertility or the unborn child.*

· **Date of preparation / last revision** 06/06/2021 / 3

· **Abbreviations and acronyms:**

*ADR: Accord relatif au transport international 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*

*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)*

*NFPA: National Fire Protection Association (USA)*

*HMS: 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*

*NIOSH: National Institute for Occupational Safety*

*OSHA: Occupational Safety & Health*

*TLV: Threshold Limit Value*

*PEL: Permissible Exposure Limit*

*REL: Recommended Exposure Limit*

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

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

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

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

*Repr. 1B: Reproductive toxicity – Category 1B*

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

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