



**Safety Data Sheet
according to HPR, Schedule 1**

Printing date 09/21/2023

Reviewed on 09/21/2023

1 Identification

· **Product identifier**

· **Trade name:** Venus Bulk Flow ONE

· -

· **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)

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

2 Hazard identification

· **Classification of the substance or mixture**

Skin Irritation - Category 2

H315 Causes skin irritation.

Eye Irritation - Category 2A

H319 Causes serious eye irritation.

Skin Sensitizer - Category 1

H317 May cause an allergic skin reaction.

Reproductive Toxicity - Category 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-diazahexadecane-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**

Avoid release to the environment.

Wear protective gloves / eye protection.

Wear protective clothing.

If on skin: Wash with plenty of soap and water.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If skin irritation or rash occurs: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

Take off contaminated clothing and wash it before reuse.

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



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

| | | |
|------------|---|----------------|
| HEALTH | 2 | Health = 2 |
| FIRE | 1 | Fire = 1 |
| REACTIVITY | 0 | Reactivity = 0 |

- **Other hazards -**

3 Composition/Information on ingredients

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

- **Dangerous components:**

| | | |
|------------|--|------------------|
| 72869-86-4 | 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahehexadecane-1,16-diyl bismethacrylate Skin Sensitizer - Category 1B, H317 | 10-25% w/w * |
| 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-<20% w/w * |
| 109-16-0 | triethylen glycol dimethacrylate Skin Sensitizer - Category 1B, H317 | ≥0,1-<0,2% w/w * |
| 21245-02-3 | 2-ethylhexyl 4-(dimethylamino)benzoate Reproductive Toxicity - Category 1B, H360 | ≥0,1-<0,2% w/w * |

* Actual concentration ranges are withheld as a trade secret.

- **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** 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** Allergic reactions
 - **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

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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:** Prevent seepage into sewage system, workpits and cellars.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **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**
No special measures required.
Ensure good ventilation/exhaustion at the workplace.
 - **Information about protection against explosions and fires:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
- **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.
- **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.

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- **Breathing equipment:** Not necessary if room is well-ventilated.
- **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
 - **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:** Tightly sealed goggles.
- **Body protection:** Light weight protective clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

- **Form:** Pasty
- **Color:** Whitish
- **Odor:** Odorless
- **Odor threshold:** Not determined.

· **pH-value:** Not determined.

· **Change in condition**

- **Melting point/Melting range:** undetermined
- **Boiling point/Boiling range:** 140 °C (284 °F)

· **Flash point:** >100 °C (>212 °F)

· **Flammability (solid, gaseous)** Not applicable.

· **Decomposition temperature:** Not determined.

· **Ignition temperature:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.
Not determined.

· **Explosion limits:**

- **Lower:** Not determined.
- **Upper:** Not determined.

· **Vapor pressure:** Not determined.

· **Density at 20 °C (68 °F):** 1,9 g/cm³ (15,8555 lbs/gal)
· **Relative density** Not determined.

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| | |
|---|--|
| · 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. |
| · 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: | | |
| 41637-38-1 bisphenol A polyethnylene glycol diether dimethacrylate | | |
| Oral | LD50 | >2.000 mg/kg (rat) (OECD 423) read-across |
| Dermal | LD50 | >2.000 mg/kg (rat) (OECD 402) read-across |
| 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 | >5.000 mg/kg (rat) (OECD 401) |
| Dermal | LD50 | >2.000 mg/kg (rat) (OECD 402) |
| 131-57-7 Oxybenzone | | |
| Oral | LD50 | >12.800 mg/kg (rat) (OECD 401) |
| Dermal | LD50 | >16.000 mg/kg (rabbit) (OECD 402) |
| 109-16-0 triethylen glycol dimethacrylate | | |
| Oral | LD50 | 8.300 mg/kg (rat) weight of evidence |
| Dermal | LD50 | >2.000 mg/kg (mouse) |
| 21245-02-3 2-ethylhexyl 4-(dimethylamino)benzoate | | |
| Oral | LD50 | 14.900 mg/kg (rat) |

- **Sensitization:** No sensitizing effects known.

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· **Additional toxicological information:**

· **Carcinogenic categories**

| | | |
|---|-----------------------|---|
| · IARC (International Agency for Research on Cancer) | | |
| 13760-80-0 | ytterbium trifluoride | 3 |

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

| | | |
|--|-------------------|-----------------------------------|
| · Reproductive toxicity | | |
| 21245-02-3 2-ethylhexyl 4-(dimethylamino)benzoate | | |
| Oral | NOAEL (Fertility) | 50 mg/kg/d /64 d (rat) (OECD 421) |

12 Ecological information

· **Toxicity**

| | |
|--|------------------------------------|
| · Aquatic toxicity: | |
| 41637-38-1 bisphenol A polyethnylene glycol diether dimethacrylate | |
| EC50/72h | >100 mg/l (algae) (OECD 201) |
| LL50/96h | >100 mg/L (fish) (OECD 203) |
| EL50/48h | >100 mg/L (daphnia) (OECD 202) |
| EL50/72h | >100 mg/L (algae) (OECD 201) |
| NOEC / 21d | ≥22,4 mg/l (daphnia) (OECD 211) |
| NOEC 28d | 14,3 mg/l (bacteria) |
| NOELR | 100 mg/L /48h (daphnia) (OECD 202) |
| 72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahehexadecane-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) |
| 131-57-7 Oxybenzone | |
| EC50/48h | 1,87 mg/l (daphnia) (OECD 202) |
| LC50/96h | 3,8 mg/l (fish) (OECD 203) |
| ErC50 / 72 h | 0,67 mg/l (algae) (OECD 201) |
| NOEC / 72h | 0,18 mg/l (algae) (OECD 201) |
| NOEC / 96h | 0,72 mg/l (fish) (OECD 203) |
| NOEC / 48h | 1,15 mg/l (daphnia) (OECD 202) |
| 109-16-0 triethylen glycol dimethacrylate | |
| EC50/21d | 51,9 mg/L (daphnia) (OECD 211) |
| LC50/96h | 16,4 mg/l (fish) (OECD 203) |
| NOEC / 21d | 32 mg/l (daphnia) (OECD 211) |
| ErC50 / 72 h | >100 mg/l (algae) (OECD 201) |
| NOEC / 72h | 18,6 mg/l (algae) (OECD 201) |
| EbC50 / 72h | 72,8 mg/l (algae) (OECD 201) |

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· Persistence and degradability

41637-38-1 bisphenol A polyethnylene glycol diether dimethacrylate

biodegradability 24 % /28d (not defined) (OECD 301D)

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

biodegradability 22 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)

131-57-7 Oxybenzone

biodegradability 60-70 % /28d (not defined)

109-16-0 triethylen glycol dimethacrylate

biodegradability 85 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)

· Behavior in environmental systems:

· Bioaccumulative potential

131-57-7 Oxybenzone

Bloconcentration factor (BCF) >33-<160 (fish) (OECD 305)

· 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

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

Disposal must be made according to official regulations.

· Uncleaned packagings:

· Recommendation:

Disposal must be made according to official regulations.

Non contaminated packagings can be used for recycling.

14 Transport information

· UN-Number

· DOT/TDG, ADR, IMDG, IATA Void

· UN proper shipping name

· DOT/TDG, ADR, IMDG, IATA Void

· Transport hazard class(es)

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

· Packing group

· DOT/TDG, ADR, IMDG, IATA Void

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- | | |
|--|-----------------|
| · 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. |
| · Transport/Additional information: | - |
| · UN "Model Regulation": | 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.
- **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.
 - H319 Causes serious eye irritation.
 - H335 May cause respiratory irritation.
 - H360 May damage fertility or the unborn child.
- **Date of the latest revision of the safety data sheet 09/21/2023**
- **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
 - 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.**