

# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 17.11.2022

Version number 1

Revision: 17.11.2022

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

- **1.1 Product identifier**
- **Trade name: AlignerFlow LC**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** Dental filling material
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
VOCO GmbH  
Anton-Flettner-Str. 1-3  
D-27472 Cuxhaven
- **Further information obtainable from:** Scientific department tel. +49 (0)4721-719-0
- **1.4 Emergency telephone number:** Poison Control Center Mainz +49 (0)6131-19240

### SECTION 2: Hazards identification

- **2.2 Label elements**
- **Classification according to Regulation (EC) No 1272/2008**  
Skin Sens. 1 H317 May cause an allergic skin reaction.
- **Labelling according to Regulation (EC) No 1272/2008**  
As a medical device the product is not subject to labelling regulations under 1272/2008/EC.
- **Hazard pictograms** GHS07
- **Signal word** Warning
- **Hazard statements**  
May cause an allergic skin reaction.
- **Precautionary statements**  
Avoid breathing dust/fume/gas/mist/vapours/spray.  
Wear protective gloves.  
Take off contaminated clothing and wash it before reuse.  
If skin irritation or rash occurs: Get medical advice/attention.  
Specific treatment (see on this label).  
Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Additional information:**  
Contains BIS GMA, Triethylene glycol dimethacrylate. May produce an allergic reaction.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 1565-94-2	BIS GMA ----- Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	2.5-5%
CAS: 109-16-0 EINECS: 203-652-6	Triethylene glycol dimethacrylate ----- Skin Sens. 1, H317	2.5-5%

### SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **After inhalation:** Seek medical treatment 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.

(Contd. on page 2)

**Safety data sheet**  
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**Trade name: AlignerFlow LC**

(Contd. of page 1)

- **After swallowing:** *If symptoms persist 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 extinguishing methods suitable to surrounding conditions.*
- **5.2 Special hazards arising from the substance or mixture** *No further relevant information available.*
- **5.3 Advice for firefighters**
- **Protective equipment:** *No special measures required.*

### **SECTION 6: Accidental release measures**

- **6.1 Personal precautions, protective equipment and emergency procedures** *Not required.*
- **6.2 Environmental precautions:** *No special measures required.*
- **6.3 Methods and material for containment and cleaning up:** *Pick up mechanically.*
- **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 disposal information.*

### **SECTION 7: Handling and storage**

- **7.1 Precautions for safe handling**  
*For dental use only.*  
*No special precautions are necessary if used correctly.*  
*Follow the instructions for use.*
- **Information about fire - and explosion protection:** *No special measures required.*
- **7.2 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:** *See storage instructions on package*
- **7.3 Specific end use(s)** *No further relevant information available.*

### **SECTION 8: Exposure controls/personal protection**

- **8.1 Control parameters**
- **Additional information about design of technical facilities:** *No further data; see item 7.*
- **Ingredients 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 valid during the making were used as basis.*
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
*The usual precautionary measures are to be adhered to when handling chemicals.*
- **Respiratory protection:** *Not required.*

(Contd. on page 3)

GB

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(Contd. of page 2)

**· Protection of hands:**

Protective gloves

**· 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.

### SECTION 9: Physical and chemical properties

**· 9.1 Information on basic physical and chemical properties****· General Information****· Appearance:**

**Form:** Pasty  
**Colour:** According to product specification  
**· Odour:** Characteristic

**· pH-value:** Not determined.**· Change in condition**

**Melting point/freezing point:** Undetermined.  
**Initial boiling point and boiling range:** Undetermined.

**· Flash point:** Not applicable.**· Auto-ignition temperature:** Product is not selfigniting.**· Explosive properties:** Product does not present an explosion hazard.**· Density:** Not determined.**· Solubility in / Miscibility with water:** Not miscible or difficult to mix.**· Viscosity:**

**Dynamic:** Not determined.  
**Kinematic:** Not determined.

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

### SECTION 10: Stability and reactivity

**· 10.1 Reactivity** No further relevant information available.**· 10.2 Chemical stability****· Thermal decomposition / conditions to be avoided:** No decomposition if used 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:** No dangerous decomposition products known.

### SECTION 11: Toxicological information

**· 11.1 Information on toxicological effects****· Acute toxicity** Based on available data, the classification criteria are not met.

(Contd. on page 4)

**Safety data sheet**  
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**Trade name: AlignerFlow LC**

(Contd. of page 3)

- **Primary irritant effect:**
- **Skin corrosion/irritation**  
Testing according to ISO 10993-1/10993-10 showed no skin irritation for this product when fully cured
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation**  
May cause an allergic skin reaction.
- **Additional toxicological information:**
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

### SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **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:** Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
- **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**  
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### SECTION 14: Transport information

- |  |      |
|--|------|
| · <b>14.1 UN-Number</b>                  |      |
| · <b>ADR, ADN, IMDG, IATA</b>            | Void |
| · <b>14.2 UN proper shipping name</b>    |      |
| · <b>ADR, ADN, IMDG, IATA</b>            | Void |
| · <b>14.3 Transport hazard class(es)</b> |      |
| · <b>ADR, ADN, IMDG, IATA</b>            |      |
| · <b>Class</b>                           | Void |
| · <b>14.4 Packing group</b>              |      |
| · <b>ADR, IMDG, IATA</b>                 | Void |
| · <b>14.5 Environmental hazards:</b>     |      |
| · <b>Marine pollutant:</b>               | No   |

(Contd. on page 5)

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(Contd. of page 4)

- |  |                        |
|--|------------------------|
| · <b>14.6 Special precautions for user</b>                                       | <i>Not applicable.</i> |
| · <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b> | <i>Not applicable.</i> |
| · <b>UN "Model Regulation":</b>  | <i>Void</i>            |

### **SECTION 15: Regulatory information**

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** *None of the ingredients is listed.*

### **SECTION 16: Other information**

*This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.*

- **Department issuing SDS:** *Scientific department*
- **Contact:** *Tel.: +49 (0)4721-719-0*
- **Abbreviations and acronyms:**  
*Skin Irrit. 2: Skin corrosion/irritation – Category 2*  
*Eye Irrit. 2: Serious eye damage/eye irritation – Category 2*  
*Skin Sens. 1: Skin sensitisation – Category 1*

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