

# Safety data sheet

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

Printing date 27.10.2016

Version number 15

Revision: 27.10.2016

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

- **1.1 Product identifier**
- **Trade name:** *Amaris*
- **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

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
*Skin Sens. 1 H317 May cause an allergic skin reaction.*
- **2.2 Label elements**
- **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*
- **Hazard statements**  
*May cause an allergic skin reaction.*
- **Precautionary statements**  
*Wear protective gloves / protective clothing.*  
*If skin irritation or rash occurs: Get medical advice/attention.*  
*IF ON SKIN: Wash with plenty of water.*  
*Take off contaminated clothing and wash it before reuse.*  
*Dispose of contents/container in accordance with local/regional/national/international regulations.*
- **2.3 Other hazards** *Use only for intended scope of application*
- **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 <i>Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317</i>	5-10%
CAS: 72869-86-4 EINECS: 276-957-5	Urethanedimethacrylate <i>Aquatic Chronic 3, H412</i>	5-10%
CAS: 109-16-0 EINECS: 203-652-6	Triethylene glycol dimethacrylate <i>Skin Sens. 1, H317</i>	≤ 2.5%

### SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** *No special measures required.*
- **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

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

Printing date 27.10.2016

Version number 15

Revision: 27.10.2016

**Trade name: Amaris**

(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:**  
*CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.*
- **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:** *Do not allow to enter sewers/ surface or ground water.*
- **6.3 Methods and material for containment and cleaning up:** *Pick up mechanically.*
- **6.4 Reference to other sections** *No dangerous substances are released.*

### SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** *For dental use only.*
- **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

- **Additional information about design of technical facilities:** *No further data; see item 7.*
- **8.1 Control parameters**
- **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.*
- **Protection of hands:**



Protective gloves

- **Material of gloves**

(Contd. on page 3)

GB

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 27.10.2016

Version number 15

Revision: 27.10.2016

**Trade name: Amaris**

(Contd. of page 2)

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.

- **Eye protection:** Not required.

### SECTION 9: Physical and chemical properties

#### · 9.1 Information on basic physical and chemical properties

##### · General Information

##### · Appearance:

· <b>Form:</b>	Pasty
· <b>Colour:</b>	According to product specification
· <b>Odour:</b>	Characteristic

· **pH-value:** Not applicable.

##### · Change in condition

· **Melting point/Melting range:** Undetermined.

· **Boiling point/Boiling range:** Undetermined.

· **Flash point:** Not applicable.

· **Self-igniting:** Product is not selfigniting.

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

· **Density:** Not determined.

· **Solubility in / Miscibility with water:** Insoluble.

##### · Viscosity:

· **Dynamic:** Not applicable.

· **Kinematic:** Not applicable.

· **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.

##### · 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.

##### · CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

· **Germ cell mutagenicity** Based on available data, the classification criteria are not met.

(Contd. on page 4)

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 27.10.2016

Version number 15

Revision: 27.10.2016

**Trade name:** Amaris

(Contd. of page 3)

- **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  
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **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              |
| · <b>14.6 Special precautions for user</b>                                       | Not applicable. |
| · <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b> | Not applicable. |
| · <b>UN "Model Regulation":</b>  | Void            |

GB

(Contd. on page 5)

**Safety data sheet**  
**according to 1907/2006/EC, Article 31**

Printing date 27.10.2016

Version number 15

Revision: 27.10.2016

Trade name: *Amaris*

(Contd. of page 4)

**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:**  
*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*  
*IATA: International Air Transport Association*  
*GHS: Globally Harmonised System of Classification and Labelling of Chemicals*  
*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)*  
*PBT: Persistent, Bioaccumulative and Toxic*  
*vPvB: very Persistent and very Bioaccumulative*  
*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*  
*Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3*
- **\* Data compared to the previous version altered.**

GB