

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

Printing date 27.10.2021

Version number 16

Revision: 27.10.2021

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

- **2.2 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.
- **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 Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	5-10%
CAS: 72869-86-4 EINECS: 276-957-5	Urethanedimethacrylate Skin Sens. 1B, H317 Aquatic Chronic 3, H412	5-10%
CAS: 109-16-0 EINECS: 203-652-6	Triethylene glycol dimethacrylate Skin Sens. 1, H317	≤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.*

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- **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:** 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:** 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.
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.
- **Protection of hands:**



Protective gloves

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- **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** Not applicable.
- **Eye protection:** Not required.

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 applicable.

· 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:

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.

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- **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
- **Additional toxicological information:**
- **CMR effects (carcinogenity, 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
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

- | | |
|--|-----------------|
| · 14.1 UN-Number | |
| · ADR, ADN, IMDG, IATA | Void |
| · 14.2 UN proper shipping name | |
| · ADR, ADN, IMDG, IATA | Void |
| · 14.3 Transport hazard class(es) | |
| · ADR, ADN, IMDG, IATA | |
| · Class | Void |
| · 14.4 Packing group | |
| · ADR, IMDG, IATA | Void |
| · 14.5 Environmental hazards: | |
| · Marine pollutant: | No |
| · 14.6 Special precautions for user | Not applicable. |

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

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

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

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