Safety Data Sheet
acc. to OSHA HCS

Printing date 10/27/2016 *Reviewed on 10/27/2016*

1 Identification

· **Product identifier**

· **Trade name: Amaris**
· **Application of the substance / the mixture** Dental filling material

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
VOCO GmbH
Anton-Flettner-Str. 1-3
D-27472 Cuxhaven

· **Information department:** Scientific department tel. +49 (0)4721-719-0
· **Emergency telephone number:** Scientific department tel. +49 (0)4721-719-0

2 Hazard(s) identification

Health effects are based on the unmixed/uncured material.
Under FDA regulations this product is classified as a medical device.
Medical devices are exempt from the labelling provisions of GHS according to the Hazard Communication Standard (HCS).

· **Classification of the substance or mixture**



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

· **Label elements**
· **Hazard pictograms** GHS07
· **Signal word** Warning
· **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.
· **Other hazards** Use only for intended scope of application
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

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3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** Mixture of the substances listed below with nonhazardous additions.

· **Dangerous components:**		
1565-94-2	BIS GMA Skin Irrit. 2, H315; Eye Irrit. 2A, H319; Skin Sens. 1, H317	5-10%
109-16-0	Triethylene glycol dimethacrylate Skin Sens. 1, H317	≤ 2.5%

4 First-aid measures

· **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.

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· **After eye contact:** Rinse opened eye for several minutes under running water.
· **After swallowing:** 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:**
CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
· **Special hazards arising from the substance or mixture** No further relevant information available.
· **Advice for firefighters**
· **Protective equipment:** No special measures required.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Not required.
· **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
· **Methods and material for containment and cleaning up:** Pick up mechanically.
· **Reference to other sections** No dangerous substances are released.

7 Handling and storage

· **Handling:**
· **Precautions for safe handling** For dental use only.
· **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:** See storage instructions on package
· **Specific end use(s)** No further relevant information available.

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8 Exposure controls/personal protection

· **Additional information about design of technical systems:** No further data; see item 7.

· **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.
· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**
· **Personal protective equipment:**
· **General protective and hygienic measures:**
The usual precautionary measures for handling chemicals should be followed.
· **Breathing equipment:** 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.
· **Eye protection:** Not required.

9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Pasty
Color:	According to product specification
· **Odor:**	Characteristic
· **pH-value:**	Not applicable.
· **Change in condition**	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
· **Flash point:**	Not applicable.
· **Auto 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.
· **Other information**	No further relevant information available.

10 Stability and reactivity

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

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11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**
· **Primary irritant effect:**
· **on the skin:**
Testing according to ISO 10993-1/10993-10 showed no skin irritation for this product when fully cured
· **on the eye:** No irritating effect.
· **Sensitization:** Sensitization possible through skin contact.

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· **Additional toxicological information:**
The product is not subject to classification according to internally approved calculation methods for preparations:
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)**		
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.

12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Behavior in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:**
Water hazard class 1 (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.
· **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.

· **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
· **Packing group**	
· **DOT, 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.
· **UN "Model Regulation":**	Void

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15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **Sara**

· **Section 355 (extremely hazardous substances):**
None of the ingredients are listed.

· **Section 313 (Specific toxic chemical listings):**
None of the ingredients are listed.

· **TSCA (Toxic Substances Control Act):**
One or more substances contained in this material are not listed on the TSCA Inventory.
Contact VOCO for more information.

· **Proposition 65**

· **Chemicals known to cause cancer:**
None of the ingredients are listed.

· **Chemicals known to cause reproductive toxicity for females:**
None of the ingredients are listed

· **Chemicals known to cause reproductive toxicity for males:**
None of the ingredients are listed

· **Chemicals known to cause developmental toxicity:**
None of the ingredients are listed

· **Cancerogenity categories**

· **EPA (Environmental Protection Agency)**
None of the ingredients are listed

· **TLV (Threshold Limit Value established by ACGIH)**
Contact VOCO for more information.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**
None of the ingredients are listed

· **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
· **Hazard pictograms** GHS07
· **Signal word** Warning
· **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.
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16 Other information

The information contained herein is based on our present knowledge and is believed to be correct at the date issued. The information is subject to change without notice. However, all information, statements, recommendations or suggestions shall not constitute any guarantee, representation or warranty, expressed or implied.
Final determination whether the product is fit and suitable for a particular purpose and the user's method of use or application is the sole responsibility of the user.

· **Department issuing SDS:** *Scientific department*
· **Contact:** *Tel.: +49 (0)4721-719-0*
· **Date of preparation / last revision** *10/27/2016 / 14*
· **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
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
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
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
· **** Data compared to the previous version altered.***