

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

Printing date 24.08.2016

Version number 10

Revision: 24.08.2016

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

- **1.1 Product identifier**
- **Trade name:** GrandioSO
- **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 soap and water.
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	2.5-5%
	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	
CAS: 109-16-0	Triethylene glycol dimethacrylate	2.5-5%
EINECS: 203-652-6	Skin Sens. 1, H317	
CAS: 41637-38-1	BIS-EMA	2.5-5%
EC number: 609-946-4	Aquatic Chronic 4, H413	

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.
- **After swallowing:** If symptoms persist consult doctor.

(Contd. on page 2)

GB

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

Printing date 24.08.2016

Version number 10

Revision: 24.08.2016

Trade name: GrandioSO

- (Contd. of page 1)
- **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:**
CO₂, 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:** No special measures required.
- **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:** See storage instructions on package
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **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 24.08.2016

Version number 10

Revision: 24.08.2016

Trade name: GrandioSO

(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:

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

• **pH-value:** Not determined.

• 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:

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.

• **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 (carcinogenity, mutagenicity and toxicity for reproduction)**

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

(Contd. on page 4)

GB

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

Printing date 24.08.2016

Version number 10

Revision: 24.08.2016

Trade name: GrandioSO

(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 data available
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **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** Smaller quantities can be disposed of with household waste.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- | | |
|--|-----------------|
| · 14.1 UN-Number | Void |
| · ADR, ADN, IMDG, IATA | Void |
| · 14.2 UN proper shipping name | Void |
| · ADR, ADN, IMDG, IATA | Void |
| · 14.3 Transport hazard class(es) | |
| · ADR, ADN, IMDG, IATA | Void |
| · 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. |
| · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · UN "Model Regulation": | Void |

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.

(Contd. on page 5)

GB

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

Printing date 24.08.2016

Version number 10

Revision: 24.08.2016

Trade name: GrandioSO

· REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

(Contd. of page 4)

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 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4

· *** Data compared to the previous version altered.**

GB

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

Printing date 02.11.2016

Version number 6

Revision: 02.11.2016

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

- **1.1 Product identifier**
- **Trade name:** Futurabond DC Liquid 1
- **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** Bonding
- **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 Corr. 1B H314 Causes severe skin burns and eye damage.
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** GHS05, GHS07
- **Hazard statements**
Causes severe skin burns and eye damage.
May cause an allergic skin reaction.
- **Precautionary statements**
Wear protective gloves / eye protection.
Wear protective clothing.
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 ON SKIN: Wash with plenty of water.
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:**

	Acidic adhesive monomer Skin Corr. 1B, H314 Eye Irrit. 2, H319	50-100%
CAS: 1565-94-2	BIS GMA Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	5-10%
CAS: 868-77-9 EINECS: 212-782-2	2-hydroxyethyl methacrylate Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	5-10%

GB

(Contd. on page 2)

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

Printing date 02.11.2016

Version number 6

Revision: 02.11.2016

Trade name: Futurabond DC Liquid 1

(Contd. of page 1)

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** Immediately remove any clothing soiled by the product.
- **After inhalation:** Supply fresh air and to be sure call for a doctor.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.
- **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:**
CO₂, 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** Ensure adequate ventilation
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Use neutralising agent.
Ensure adequate ventilation.
- **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.
- **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:**
Keep container tightly sealed.
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.

(Contd. on page 3)

GB

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

Printing date 02.11.2016

Version number 6

Revision: 02.11.2016

Trade name: Futurabond DC Liquid 1

(Contd. of page 2)

- **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:** Avoid contact with the eyes and skin.
- **Respiratory protection:** Not required.
- **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.
- **Eye protection:** Safety glasses

SECTION 9: Physical and chemical properties

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

Form:	Fluid
Colour:	According to product specification
- **Odour:** Characteristic
- **Odour threshold:** Not determined.
- **pH-value at 20 °C:** 1.5
- **Change in condition**

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
- **Flash point:** Not applicable.
- **Flammability (solid, gaseous):** Not applicable.
- **Decomposition temperature:** Not determined.
- **Self-igniting:** Product is not selfigniting.
- **Danger of explosion:** Product does not present an explosion hazard.
- **Density at 20 °C:** 1.2 g/cm³
- **Relative density** Not determined.
- **Vapour 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.

(Contd. on page 4)

GB

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

Printing date 02.11.2016

Version number 6

Revision: 02.11.2016

Trade name: Futurabond DC Liquid 1

(Contd. of page 3)

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.

· LD/LC50 values relevant for classification:

Acidic adhesive monomer

Oral LD50 > 2000 mg/kg (rat)

- Primary irritant effect:
- Skin corrosion/irritation
Testing according to ISO 10993-1/10993-10 showed no skin irritation for this product when fully cured
Causes severe skin burns and eye damage.
- Serious eye damage/irritation
Causes severe skin burns and eye damage.
- 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.
- 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.

GB

(Contd. on page 5)

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

Printing date 02.11.2016

Version number 6

Revision: 02.11.2016

Trade name: Futurabond DC Liquid 1

(Contd. of page 4)

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 | - |
| · 14.2 UN proper shipping name | - |
| · 14.3 Transport hazard class(es) | - |
| · 14.4 Packing group | - |
| · 14.5 Environmental hazards: | |
| · Marine pollutant: | No |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |

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.
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

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:**
 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)
 LC50: Lethal concentration, 50 percent
 LD50: Lethal dose, 50 percent
 PBT: Persistent, Bioaccumulative and Toxic
 vPvB: very Persistent and very Bioaccumulative
 Skin Corr. 1B: Skin corrosion/irritation – Category 1B
 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
 STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
- *** Data compared to the previous version altered.**

GB

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

Printing date 02.11.2016

Version number 6

Revision: 02.11.2016

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

- **1.1 Product identifier**
- **Trade name:** Futurabond DC Liquid 2
- **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** Bonding
- **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**
Flam. Liq. 2 H225 Highly flammable liquid and vapour.
- **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** GHS02
- **Hazard statements**
Highly flammable liquid and vapour.
- **Precautionary statements**
Wear protective gloves / protective clothing.
If skin irritation occurs: Get medical advice/attention.
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: 64-17-5	ethanol	Flam. Liq. 2, H225	50-100%
EINECS: 200-578-6			
	Initiator	Acute Tox. 3, H301	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.
- **After swallowing:** If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.

(Contd. on page 2)

GB

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

Printing date 02.11.2016

Version number 6

Revision: 02.11.2016

Trade name: Futurabond DC Liquid 2

(Contd. of page 1)

- **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:** CO₂, sand, extinguishing powder. Do not use water.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **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** Wear protective clothing.
- **6.2 Environmental precautions:**
Do not allow to enter sewers/ surface or ground water.
Dilute with plenty of water.
- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **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.
- **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:**
Keep container tightly sealed.
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.

(Contd. on page 3)

GB

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

Printing date 02.11.2016

Version number 6

Revision: 02.11.2016

Trade name: Futurabond DC Liquid 2

(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.

· **Eye protection:** Safety glasses

SECTION 9: Physical and chemical properties

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

· **General Information**

· **Appearance:**

Form: Fluid

Colour: Colourless

· **Odour:** Characteristic

· **pH-value:** Not determined.

· **Change in condition**

Melting point/Melting range: Undetermined.

Boiling point/Boiling range: Undetermined.

· **Flash point:** 21 °C

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

· **Danger of explosion:** Product is not explosive. However, formation of explosive air/vapour mixtures are possible.

· **Density at 20 °C:** 0.87 g/cm³

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

Fully miscible.

· **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)

GB

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

Printing date 02.11.2016

Version number 6

Revision: 02.11.2016

Trade name: Futurabond DC Liquid 2

(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** Based on available data, the classification criteria are not met.
- **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:**
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 | UN1170 |
| · ADR, IMDG, IATA | |
| · 14.2 UN proper shipping name | 1170 ETHANOL (ETHYL ALCOHOL) mixture |
| · ADR | ETHANOL (ETHYL ALCOHOL) mixture |
| · IMDG | ETHANOL mixture |
| · IATA | |
| · 14.3 Transport hazard class(es) | |
| · ADR, IMDG, IATA | |
|  | |
| · Class | 3 Flammable liquids. |
| · Label | 3 |

(Contd. on page 5)

GB

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

Printing date 02.11.2016

Version number 6

Revision: 02.11.2016

Trade name: Futurabond DC Liquid 2

(Contd. of page 4)

· 14.4 Packing group	
· ADR, IMDG, IATA	II
· 14.5 Environmental hazards:	
· Marine pollutant:	No
· 14.6 Special precautions for user	Warning: Flammable liquids.
· Danger code (Kemler):	33
· EMS Number:	F-E,S-D
· Stowage Category	A
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADR	
· Limited quantities (LQ)	1L
· Transport category	2
· Tunnel restriction code	D/E
· UN "Model Regulation":	UN 1170 ETHANOL (ETHYL ALCOHOL) MIXTURE, 3, II

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.
- Seveso category P5c FLAMMABLE LIQUIDS
- Qualifying quantity (tonnes) for the application of lower-tier requirements 5,000 t
- Qualifying quantity (tonnes) for the application of upper-tier requirements 50,000 t
- REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

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
 Flam. Liq. 2: Flammable liquids – Category 2
 Acute Tox. 3: Acute toxicity – Category 3

- * Data compared to the previous version altered.

GB

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

Printing date 21.03.2017

Version number 9

Revision: 21.03.2017

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

- **1.1 Product identifier**
- **Trade name:** Die silicone catalyst
- **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**
Extraoral fabrication of cavity models and models of individual, or groups of teeth
- **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**
The product is not classified according to the CLP regulation.
- **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** Void
- **Hazard statements** Void
- **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 non-hazardous substances.
- **Dangerous components:** Void

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** No special measures required.
- **After skin contact:** Generally the product does not irritate the skin.
- **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:**
CO₂, 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.

(Contd. on page 2)

GB

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

Printing date 21.03.2017

Version number 9

Revision: 21.03.2017

Trade name: Die silicone catalyst

(Contd. of page 1)

- 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
- 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.
 - 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
Keep container tightly sealed.
- 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: Usual protective and hygienic measures for dental practice.
 - Respiratory protection: Not required.
 - Protection of hands: Not required.
 - Material of gloves 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: | Violet |
| Odour: | Characteristic |
| Odour threshold: | Not determined. |

(Contd. on page 3)

GB

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

Printing date 21.03.2017

Version number 9

Revision: 21.03.2017

Trade name: Die silicone catalyst

(Contd. of page 2)

· pH-value:	Not determined.
· Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
· Flash point:	Not applicable.
· Flammability (solid, gaseous):	Not applicable.
· Decomposition temperature:	Not determined.
· Self-igniting:	Product is not selfigniting.
· Danger of explosion:	Product does not present an explosion hazard.
· Density:	Not determined.
· Relative density	Not determined.
· Vapour 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.
· 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 Based on available data, the classification criteria are not met.
- Serious eye damage/irritation Based on available data, the classification criteria are not met.
- Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- 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.

(Contd. on page 4)

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

Printing date 21.03.2017

Version number 9

Revision: 21.03.2017

Trade name: Die silicone catalyst

(Contd. of page 3)

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	Void
· 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	Void
· Class	Void
· 14.4 Packing group	-
· ADR, IMDG, IATA	Void
· 14.5 Environmental hazards:	Not applicable.
· Marine pollutant:	No
· 14.6 Special precautions for user	Not applicable.
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· UN "Model Regulation":	Void

(Contd. on page 5)

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

Printing date 21.03.2017

Version number 9

Revision: 21.03.2017

Trade name: Die silicone catalyst

(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
- * Data compared to the previous version altered.

GB

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

Printing date 17.11.2016

Version number 6

Revision: 25.02.2016

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

- **1.1 Product identifier**
- **Trade name:** Meron Plus (AC) liquid
- **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**
Eye Irrit. 2 H319 Causes serious eye irritation.
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**
Causes serious eye irritation.
May cause an allergic skin reaction.
- **Precautionary statements**
Wear protective gloves / eye protection.
Wear protective clothing.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
IF INHALED: Remove person to fresh air and keep comfortable for breathing.
If skin irritation or rash occurs: Get medical advice/attention.
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: 868-77-9	2-hydroxyethyl methacrylate	25-50%
EINECS: 212-782-2	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	
CAS: 1830-78-0	Glycerindimethacrylate	2.5-5%
EINECS: 217-388-4	Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	
CAS: 72869-86-4	Urethanedimethacrylate	≤ 2.5%
EINECS: 276-957-5	Aquatic Chronic 3, H412	

(Contd. on page 2)

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

Printing date 17.11.2016

Version number 6

Revision: 25.02.2016

Trade name: **Meron Plus (AC) liquid**

(Contd. of page 1)

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. If symptoms persist, consult a doctor.
- **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:**
CO₂, 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:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **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.
- **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.

(Contd. on page 3)

GB

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

Printing date 17.11.2016

Version number 6

Revision: 25.02.2016

Trade name: **Meron Plus (AC) liquid**

(Contd. of page 2)

- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
Avoid contact with the eyes and skin.
- **Respiratory protection:** Not required.
- **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.
- **Eye protection:** Safety glasses

SECTION 9: Physical and chemical properties

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

Form:	Fluid
Colour:	Yellowish
Odour:	Characteristic
- **pH-value:** Not determined.
- **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:** Fully miscible.
- **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.

(Contd. on page 4)

GB

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

Printing date 17.11.2016

Version number 6

Revision: 25.02.2016

Trade name: Meron Plus (AC) liquid

(Contd. of page 3)

· 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
Causes serious eye irritation.
- 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.
- 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.
- Recommended cleansing agents: Water, if necessary together with cleansing agents.

SECTION 14: Transport information

- 14.1 UN-Number
- ADR, ADN, IMDG, IATA

Void

(Contd. on page 5)

GB

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

Printing date 17.11.2016

Version number 6

Revision: 25.02.2016

Trade name: **Meron Plus (AC) liquid**

(Contd. of page 4)

· 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.
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· UN "Model Regulation":	Void

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.
- REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

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
 STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
 Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3
- * Data compared to the previous version altered.

GB

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 17.11.2016

Version number 6

Revision: 17.11.2016

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

- 1.1 Product identifier
- Trade name: **Meron Plus (AC) powder**
- 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 luting cement
- 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
The product is not classified according to the CLP regulation.
- 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 Void
- Hazard statements Void
- 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:

	fluoro-aluminosilicate glass	Eye Irrit. 2, H319	50-100%
CAS: 87-69-4 EINECS: 201-766-0	(+)-tartaric acid	Eye Dam. 1, H318	≤ 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.
- 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.

(Contd. on page 2)

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

Printing date 17.11.2016

Version number 6

Revision: 17.11.2016

Trade name: Meron Plus (AC) powder

(Contd. of page 1)

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, 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:** Not required.
- **Material of gloves** Not applicable.

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**
- **Form:** Solid
- **Colour:** Whitish
- **Odour:** Characteristic

(Contd. on page 3)

GB

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

Printing date 17.11.2016

Version number 6

Revision: 17.11.2016

Trade name: Meron Plus (AC) powder

(Contd. of page 2)

· 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.
· Solids content:	100.0 %
· 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 Based on available data, the classification criteria are not met.
- 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.

(Contd. on page 4)

GB

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

Printing date 17.11.2016

Version number 6

Revision: 17.11.2016

Trade name: **Meron Plus (AC) powder**

(Contd. of page 3)

- **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** Smaller quantities can be disposed of with household waste.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

SECTION 14: Transport information

- | | |
|--|-----------------|
| · 14.1 UN-Number | Void |
| · ADR, ADN, IMDG, IATA | |
| · 14.2 UN proper shipping name | Void |
| · ADR, ADN, IMDG, IATA | |
| · 14.3 Transport hazard class(es) | |
| · ADR, ADN, IMDG, IATA | Void |
| · Class | |
| · 14.4 Packing group | Void |
| · ADR, IMDG, IATA | |
| · 14.5 Environmental hazards: | No |
| · Marine pollutant: | |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · UN "Model Regulation": | Void |

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

(Contd. on page 5)

GB

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

Printing date 17.11.2016

Version number 6

Revision: 17.11.2016

Trade name: Meron Plus (AC) powder

(Contd. of page 4)

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

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

*** Data compared to the previous version altered.**

GB

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

Printing date 21.03.2017

Version number 8

Revision: 21.03.2017

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

- **1.1 Product identifier**
- **Trade name:** Die silicone base
- **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**
Extraoral fabrication of cavity models and models of individual, or groups of teeth
- **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**
The product is not classified according to the CLP regulation.
- **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** Void
- **Hazard statements** Void
- **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 non-hazardous substances.
- **Dangerous components:** Void

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** No special measures required.
- **After skin contact:** Generally the product does not irritate the skin.
- **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:**
CO₂, 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.

(Contd. on page 2)

GB

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

Printing date 21.03.2017

Version number 8

Revision: 21.03.2017

Trade name: Die silicone base

(Contd. of page 1)

- 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
- 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.
- 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: Usual protective and hygienic measures for dental practice.
- Respiratory protection: Not required.
- Protection of hands: Not required.
- Material of gloves 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: Red
- Odour: Characteristic
- Odour threshold: Not determined.
- pH-value: Not determined.

(Contd. on page 3)

GB

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

Printing date 21.03.2017

Version number 8

Revision: 21.03.2017

Trade name: Die silicone base

(Contd. of page 2)

· Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
· Flash point:	Not applicable.
· Flammability (solid, gaseous):	Not applicable.
· Decomposition temperature:	Not determined.
· Self-igniting:	Product is not selfigniting.
· Danger of explosion:	Product does not present an explosion hazard.
· Density:	Not determined.
· Relative density	Not determined.
· Vapour 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.
· 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** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **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.

(Contd. on page 4)

GB

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

Printing date 21.03.2017

Version number 8

Revision: 21.03.2017

Trade name: Die silicone base

(Contd. of page 3)

- **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 | Void |
| · 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 | Void |
| · Class | Void |
| · 14.4 Packing group | - |
| · ADR, IMDG, IATA | Void |
| · 14.5 Environmental hazards: | Not applicable. |
| · Marine pollutant: | No |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · UN "Model Regulation": | Void |

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.

(Contd. on page 5)

GB

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

Printing date 21.03.2017

Version number 8

Revision: 21.03.2017

Trade name: Die silicone base

(Contd. of page 4)

· **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

· *** Data compared to the previous version altered.**

GB

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

Printing date 21.09.2016

Version number 10

Revision: 21.09.2016

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

- **1.1 Product identifier**
- **Trade name:** Bifix QM catalyst
- **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 luting cement
- **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 Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2 H319 Causes serious eye irritation.
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**
Causes skin irritation.
Causes serious eye irritation.
May cause an allergic skin reaction.
- **Precautionary statements**
Wear protective gloves / eye protection.
Wear protective clothing.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If skin irritation occurs: Get medical advice/attention.
If eye irritation persists: Get medical advice/attention.
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: 6606-59-3	1,6-hexanediylbismethacrylate	10-25%
EINECS: 229-551-7	Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	
CAS: 1565-94-2	BIS GMA	10-25%
	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	

(Contd. on page 2)

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

Printing date 21.09.2016

Version number 10

Revision: 21.09.2016

Trade name: Bifix QM catalyst

(Contd. of page 1)

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. If symptoms persist, consult a doctor.
- **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:**
CO₂, 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:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **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.
- **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.

(Contd. on page 3)

GB

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

Printing date 21.09.2016

Version number 10

Revision: 21.09.2016

Trade name: Bifix QM catalyst

(Contd. of page 2)

- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
Avoid contact with the eyes and skin.
- **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.
- **Eye protection:** Safety glasses

SECTION 9: Physical and chemical properties

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

Form:	Pasty
Colour:	Whitish
	Different according to colouring
- **Odour:** Characteristic
- **pH-value:** Not determined.
- **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:** 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.

(Contd. on page 4)

GB

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

Printing date 21.09.2016

Version number 10

Revision: 21.09.2016

Trade name: Bifix QM catalyst

(Contd. of page 3)

· 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
Causes skin irritation.
- Serious eye damage/irritation
Causes serious eye irritation.
- 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.
- 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 |

(Contd. on page 5)

GB

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

Printing date 21.09.2016

Version number 10

Revision: 21.09.2016

Trade name: Bifix QM catalyst

(Contd. of page 4)

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

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.
- REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

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
 - STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
- * Data compared to the previous version altered.

GB

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

Printing date 21.09.2016

Version number 9

Revision: 21.09.2016

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

- **1.1 Product identifier**
- **Trade name:** Bifix QM base
- **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 luting cement
- **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 Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2 H319 Causes serious eye irritation.
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**
Causes skin irritation.
Causes serious eye irritation.
May cause an allergic skin reaction.
- **Precautionary statements**
Wear protective gloves / eye protection.
Wear protective clothing.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If skin irritation occurs: Get medical advice/attention.
If eye irritation persists: Get medical advice/attention.
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	10-25%
	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	
CAS: 6606-59-3	1,6-hexanediylbismethacrylate	10-25%
EINECS: 229-551-7	Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	

(Contd. on page 2)

GB

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

Printing date 21.09.2016

Version number 9

Revision: 21.09.2016

Trade name: Bifix QM base

(Contd. of page 1)

	Catalyst Aquatic Acute 1, H400 Acute Tox. 4, H302; Acute Tox. 4, H332; Skin Irrit. 2, H315; Eye Irrit. 2, H319	$\leq 2.5\%$
--	---	--------------

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. If symptoms persist, consult a doctor.
- **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:**
CO₂, 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:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **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.
- **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.

(Contd. on page 3)

GB

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


Printing date 21.09.2016

Version number 9

Revision: 21.09.2016

Trade name: Bifix QM base

(Contd. of page 2)

- **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.
Avoid contact with the eyes and skin.
 - **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.
 - **Eye protection:** Safety glasses

SECTION 9: Physical and chemical properties

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

Form:	Pasty
Colour:	Whitish
Odour:	Characteristic
- **pH-value:** Not determined.
- **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:** 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.

(Contd. on page 4)

GB

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

Printing date 21.09.2016

Version number 9

Revision: 21.09.2016

Trade name: Bifix QM base

(Contd. of page 3)

- 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
Causes skin irritation.
- Serious eye damage/irritation
Causes serious eye irritation.
- 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.
- 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

(Contd. on page 5)

GB

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

Printing date 21.09.2016

Version number 9

Revision: 21.09.2016

Trade name: Bifix QM base

(Contd. of page 4)

· 14.2 UN proper shipping name	Void
· ADR, ADN, IMDG, IATA	
· 14.3 Transport hazard class(es)	
· ADR, ADN, IMDG, IATA	Void
· Class	
· 14.4 Packing group	Void
· ADR, IMDG, IATA	
· 14.5 Environmental hazards:	No
· Marine pollutant:	
· 14.6 Special precautions for user	Not applicable.
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· UN "Model Regulation":	Void

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.
- REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

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
 Acute Tox. 4: Acute toxicity – Category 4
 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
 STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
 Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
- * Data compared to the previous version altered.

GB