

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

071047364

**The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).**

071047356

# Safety data sheet

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

Printing date 01.03.2018

Version number 1

Revision: 01.03.2018

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

- **1.1 Product identifier**
- **Trade name:** *Meron Plus 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**  
Avoid breathing spray.  
Wear protective gloves / eye protection / face protection.  
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 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:**

	polyacrylic acid	10-25%
	Eye Irrit. 2, H319	
CAS: 868-77-9	2-hydroxyethyl methacrylate	10-25%
EINECS: 212-782-2	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	

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**Trade name: Meron Plus QM Catalyst**

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CAS: 1830-78-0 EINECS: 217-388-4	Glycerindimethacrylate Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1A, H317; STOT SE 3, H335	2.5-5%
	Katalysator Flam. Liq. 3, H226; Org. Perox. D, H242 Acute Tox. 3, H331 Skin Corr. 1B, H314 Aquatic Chronic 2, H411 Acute Tox. 4, H302; Skin Sens. 1, H317	≤2.5%

### SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **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. 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:** Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.
- **6.4 Reference to other sections**  
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.
- **7.3 Specific end use(s)** No further relevant information available.

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Trade name: **Meron Plus QM Catalyst**

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### 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:**  
Immediately remove all soiled and contaminated clothing  
Wash hands before breaks and at the end of work.  
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:	Pasty
Colour:	According to product specification
- **Odour:** Characteristic
- **Odour threshold:** Not determined.
- **pH-value:** Not applicable.
- **Change in condition**

Melting point/freezing point:	unbekannt °C
Initial boiling point and boiling range:	Undetermined.
- **Flash point:** Not applicable.
- **Flammability (solid, gas):** Not determined.
- **Decomposition temperature:** Not determined.
- **Auto-ignition temperature:** Product is not selfigniting.
- **Explosive properties:** Product does not present an explosion hazard.
- **Density:** Not determined.
- **Relative density** Not determined.
- **Vapour density** Not applicable.
- **Evaporation rate** Not applicable.
- **Solubility in / Miscibility with water:** Insoluble.

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- **Partition coefficient: n-octanol/water:** Not determined.
- **Viscosity:**
  - Dynamic:** Not applicable.
  - Kinematic:** Not applicable.
- **9.2 Other information** No further relevant information available.

### SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

### SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Primary irritant effect:**
- **Skin corrosion/irritation**  
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.

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### SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**  
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### SECTION 14: Transport information

- |  |                 |
|--|-----------------|
| · <b>14.1 UN-Number</b>  | Void            |
| · <b>ADR, ADN, IMDG, IATA</b>  | Void            |
| · <b>14.2 UN proper shipping name</b>  | -               |
| · <b>ADR, ADN, IMDG, IATA</b>  | Void            |
| · <b>14.3 Transport hazard class(es)</b>   | -               |
| · <b>ADR, ADN, IMDG, IATA</b>  |                 |
| · <b>Class</b>   | Void            |
| · <b>14.4 Packing group</b>  | -               |
| · <b>ADR, IMDG, IATA</b>   | Void            |
| · <b>14.5 Environmental hazards:</b>   | Not applicable. |
| · <b>14.6 Special precautions for user</b>                                       | Not applicable. |
| · <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b> | Not applicable. |
| · <b>UN "Model Regulation":</b>  | Void            |

### 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

- **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. 3: Flammable liquids – Category 3  
 Org. Perox. D: Organic peroxides – Type C/D  
 Acute Tox. 4: Acute toxicity – Category 4  
 Acute Tox. 3: Acute toxicity – Category 3  
 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

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*Skin Sens. 1: Skin sensitisation – Category 1**Skin Sens. 1A: Skin sensitisation – Category 1A**STOT SE 3: Specific target organ toxicity (single exposure) – Category 3**Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2*

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**Data sheet for medical devices / EU**

Printing date 03.07.2024

Version number 2 (replaces version 1)

Revision: 03.07.2024

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier****Trade name:** Meron Plus QM base**Chemical Identification:**

This product is a medical device according to Directive 93/42/EEC concerning medical devices or Regulation (EU) 2017/745 (MDR), which is used invasively or in contact with the body. Therefore, it is exempt from the classification and labelling requirements of Regulation (EC) 1272/2008 (AR CLP, Article 1, paragraph 5 d). A safety data sheet is not required by law for this product. This information is provided on a voluntary basis in the form of this Medical Devices Data Sheet.

**Product category** Dental medical device**Article category**

The information relevant for the application and for the safety of users and patients is defined in the product-specific directions for use. The instructions for use must be observed.

The product should only be applied by a professionally trained dental practitioner.

**Application of the substance / the mixture** Dental luting cement**1.3 Details of the supplier of the data sheet****Manufacturer/Supplier:**

VOCO GmbH

Anton-Flettner-Str. 1-3

D-27472 Cuxhaven

info@voco.de

+49 (0) 4721-719-0 Mo - Fr / 08:00h - 16:00h

**SECTION 2: Hazards identification****2.1 Classification of the substance or mixture****Classification according to Regulation (EC) No 1272/2008**

This product is a medical device according to Directive 93/42/EEC concerning medical devices or Regulation (EU) 2017/745 (MDR), which is used invasively or in contact with the body. Therefore, it is exempt from the classification and labelling requirements of Regulation (EC) 1272/2008 (AR CLP, Article 1, paragraph 5 d). The classification criteria of Regulation (EC) No 1272/2008 are not directly applicable to this product, but are considered by us as an orienting basis for assessment. The health and environmental hazards have been assessed and classified on the basis of the information known to us on the components and their reaction processes. The following hazards based on the classification criteria of Regulation (EC) No 1272/2008 for humans and the environment cannot be excluded:

Eye Irrit. 2 H319 Causes serious eye irritation.

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

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

**2.3 Other hazards****Results of PBT and vPvB assessment****PBT:** Not applicable.**vPvB:** Not applicable.**SECTION 3: Composition/information on ingredients****3.2 Mixtures****Description:** Mixture of substances listed below with nonhazardous additions.**Dangerous components:**

methacrylic acid, monoester with propane-1,2-diol Eye Irrit. 2, H319; Skin Sens. 1, H317	10-25%
GlyDMA Eye Irrit. 2, H319	2.5-10%
UDMA Aquatic Chronic 2, H411; Skin Sens. 1, H317	2.5-10%

**Additional information:**

Further information on ingredients can be found in the instructions for use.

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**Trade name: Meron Plus QM base**

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In case of known hypersensitivity to the ingredients mentioned in the instructions for use, do not use the product.

**SECTION 4: First aid measures**

- **4.1 Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:** Supply fresh air; consult doctor 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.  
Rinse out mouth and then drink plenty of water.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **4.3 In case of contact with mucous membranes during treatment:** No special measures required.

**SECTION 5: Firefighting measures**

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

**SECTION 6: Accidental release measures**

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:**  
Dilute with plenty of water.  
No special measures required.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).  
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**  
No special precautions are necessary if used correctly.  
For use in dental application only.  
Observe the instructions for use! This contains the relevant application and safety information for the use of this product.
- **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:**  
Please observe the storage instructions on the packaging and in the instructions for use.

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Trade name: *Meron Plus QM base*

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**SECTION 8: Exposure controls/personal protection**· **8.1 Control parameters**· **Ingredients with limit values that require monitoring at the workplace:**· **Additional information:**

Due to the proportions contained in relation to the amount of product during use and the way it is incorporated into the product, monitoring of specific, workplace-related limit values is not applicable.

· **8.2 Exposure controls**· **Individual protection measures, such as personal protective equipment**· **General protective and hygienic measures:**

The usual precautionary measures are to be adhered to when handling chemicals.

In the context of the use of this product, the hygiene standards customary and general in dental practice, such as hand, mouth and eye protection, must be applied.

**SECTION 9: Physical and chemical properties**· **9.1 Information on basic physical and chemical properties**· **General Information**· **Physical state**

Liquid

· **Colour:**

white to yellowish

· **Odour:**

Characteristic

· **Odour threshold:**

Not determined.

· **Melting point/freezing point:**

Undetermined.

· **Boiling point or initial boiling point and boiling range**

Undetermined.

· **Flammability**

Not applicable.

· **Lower and upper explosion limit**· **Lower:**

Not determined.

· **Upper:**

Not determined.

· **Flash point:**

95 °C (27813-02-1 methacrylic acid, monoester with propane-1,2-diol)

· **Decomposition temperature:**

Not determined.

· **pH**

Not determined.

· **Viscosity:**· **Kinematic viscosity**

Not determined.

· **Dynamic:**

Not determined.

· **Solubility**· **water:**

Fully miscible.

· **Partition coefficient n-octanol/water (log value)**

Not determined.

· **Vapour pressure:**

Not determined.

· **Density and/or relative density**· **Density:**

Not determined.

· **Relative density**

Not determined.

· **Vapour density**

Not determined.

· **9.2 Other information**· **Appearance:**· **Form:**

Pasty

· **Important information on protection of health and environment, and on safety.**· **Auto-ignition temperature:**

Product is not selfigniting.

· **Explosive properties:**

Product does not present an explosion hazard.

· **Solvent content:**· **Solids content:**

72.5 %

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**Trade name: Meron Plus QM base**

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**· Change in condition**

*After mixing the base and catalyst paste, the product cures according to the product description and instructions for use.*

**SECTION 10: Stability and reactivity****· 10.1 Reactivity**

*After mixing the base and catalyst paste, the product cures according to the product description and instructions for use.*

**· 10.2 Chemical stability** *Stable.***· 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****· Other information**

*As an invasive medical device, the product is subject to relevant laws and standards which ensure the safety and performance of the product when used appropriately and in accordance with the instructions for use. Specific toxicological information is not applicable at this point. The instructions for use must be observed.*

**SECTION 12: Ecological information****· General notes:**

*As an invasive medical device, the product is subject to relevant laws and standards that ensure the safety and performance of the product when used properly and in accordance with the instructions for use. Special environmental information is not applicable at this point. The instructions for use must be observed.*

**SECTION 13: Disposal considerations****· 13.1 Waste treatment methods****· Recommendation** *Dispose of in accordance with official regulations.***· Uncleaned packaging:****· Recommendation:** *Dispose of in accordance with official regulations.***· Recommended cleansing agents:** *Water, if necessary together with cleansing agents.***SECTION 14: Transport information****· 14.1 UN number or ID number****· ADR, IMDG, IATA***Void***· 14.2 UN proper shipping name****· ADR, 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:***Not applicable.*

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- |   |                 |
|---|-----------------|
| · <b>14.6 Special precautions for user</b>                            | Not applicable. |
| · <b>14.7 Maritime transport in bulk according to IMO instruments</b> | Not applicable. |
| · <b>UN "Model Regulation":</b>                                       | Void            |

**SECTION 15: Regulatory information**

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**  
Regulation (EU) 2017/745  
Medical Devices Regulation

Directive 93/42/EEC concerning medical devices

- **15.2 Chemical safety assessment:**  
The health and environmental hazards have been assessed and classified on the basis of the information known to us on the components and their reaction processes.  
A Chemical Safety Assessment has not been carried out.

**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.

The product to which this data sheet is assigned is a medical device according to the EU Medical Devices Regulation EU 2017/745. Invasive medical devices or medical devices in direct body contact are exempted from the classification and labelling requirements of Regulation (EU) 1272/2008 (AR CLP, Article 1, paragraph 5 d). The Medical Devices Regulation does not require a safety data sheet for invasive medical devices or medical devices in direct body contact, as the safe use of the product is indicated in the instructions for use and/or the labelling. Nevertheless, we provide a data sheet for medical devices in order to provide as transparent a source as possible for the assessment of hazards to humans and the environment.

- **Relevant phrases**  
H317 May cause an allergic skin reaction.  
H319 Causes serious eye irritation.  
H411 Toxic to aquatic life with long lasting effects.
- **Department issuing Datasheet:** Knowledge Communication Department
- **Contact:**  
Global headquarter:  
VOCO GmbH  
Anton-Flettner-Str. 1-3  
D-27472 Cuxhaven  
info@voco.de  
+49 (0) 4721-719-0 Mo - Fr / 08:00h - 16:00h

Australien sponsor address:  
VOCO Australia Pty Ltd  
Level 19, 133-145 Castlereagh Street  
Sydney, NSW 2000  
Email: info@voco.com

For further contact information, please visit [www.voco.dental](http://www.voco.dental)

- **Version number of previous version:** 1
- **Abbreviations and acronyms:**  
ADR: Accord relatif au transport international 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

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*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 Irrit. 2: Serious eye damage/eye irritation – Category 2**Skin Sens. 1: Skin sensitisation – Category 1**Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2**Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3*

EU

**SECTION 1: Identification of the substance/mixture and of the company/undertaking**· **1.1 Product identifier**· **Trade name:** Meron Plus QM catalyst· **Chemical Identification:**

This product is a medical device according to Directive 93/42/EEC concerning medical devices or Regulation (EU) 2017/745 (MDR), which is used invasively or in contact with the body. Therefore, it is exempt from the classification and labelling requirements of Regulation (EC) 1272/2008 (AR CLP, Article 1, paragraph 5 d). A safety data sheet is not required by law for this product. This information is provided on a voluntary basis in the form of this Medical Devices Data Sheet.

· **Product category** Dental medical device· **Article category**

The information relevant for the application and for the safety of users and patients is defined in the product-specific directions for use. The instructions for use must be observed.

The product should only be applied by a professionally trained dental practitioner.

· **Application of the substance / the mixture** Dental luting cement· **1.3 Details of the supplier of the data sheet**· **Manufacturer/Supplier:**

VOCO GmbH

Anton-Flettner-Str. 1-3

D-27472 Cuxhaven

info@voco.de

+49 (0) 4721-719-0 Mo - Fr / 08:00h - 16:00h

**SECTION 2: Hazards identification**· **2.1 Classification of the substance or mixture**· **Classification according to Regulation (EC) No 1272/2008**

This product is a medical device according to Directive 93/42/EEC concerning medical devices or Regulation (EU) 2017/745 (MDR), which is used invasively or in contact with the body. Therefore, it is exempt from the classification and labelling requirements of Regulation (EC) 1272/2008 (AR CLP, Article 1, paragraph 5 d). The classification criteria of Regulation (EC) No 1272/2008 are not directly applicable to this product, but are considered by us as an orienting basis for assessment. The health and environmental hazards have been assessed and classified on the basis of the information known to us on the components and their reaction processes. The following hazards based on the classification criteria of Regulation (EC) No 1272/2008 for humans and the environment cannot be excluded:

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.

· **2.3 Other hazards**· **Results of PBT and vPvB assessment**· **PBT:** Not applicable.· **vPvB:** Not applicable.**SECTION 3: Composition/information on ingredients**· **3.2 Mixtures**· **Description:** Mixture of substances listed below with nonhazardous additions.· **Dangerous components:**

polyacrylic acid Eye Irrit. 2, H319	10-25%
HEMA Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	10-25%
GlyDMA Eye Irrit. 2, H319	2.5-10%
Catalyst Flam. Liq. 3, H226; Org. Perox. D, H242; Acute Tox. 3, H331; Skin Corr. 1B, H314; Aquatic Chronic 2, H411; Acute Tox. 4, H302; Skin Sens. 1, H317	0.1-1%

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**· Additional information:***Further information on ingredients can be found in the instructions for use.**In case of known hypersensitivity to the ingredients mentioned in the instructions for use, do not use the product.***SECTION 4: First aid measures****· 4.1 Description of first aid measures****· General information:** *No special measures required.***· After inhalation:** *Supply fresh air; consult doctor 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.**Rinse out mouth and then drink plenty of water.***· 4.2 Most important symptoms and effects, both acute and delayed** *No further relevant information available.***· 4.3 In case of contact with mucous membranes during treatment:** *No special measures required.***SECTION 5: Firefighting measures****· 5.1 Extinguishing media****· Suitable extinguishing agents:** *Use fire extinguishing methods suitable to surrounding conditions.***· 5.2 Special hazards arising from the substance or mixture** *No further relevant information available.***· 5.3 Advice for firefighters****· Protective equipment:** *No special measures required.***SECTION 6: Accidental release measures****· 6.1 Personal precautions, protective equipment and emergency procedures** *Not required.***· 6.2 Environmental precautions:** *No special measures required.***· 6.3 Methods and material for containment and cleaning up:** *Pick up mechanically.***· 6.4 Reference to other sections***See Section 7 for information on safe handling.**See Section 8 for information on personal protection equipment.**See Section 13 for disposal information.***SECTION 7: Handling and storage****· 7.1 Precautions for safe handling***No special precautions are necessary if used correctly.**For use in dental application only.**Observe the instructions for use! This contains the relevant application and safety information for the use of this product.***· 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:***Please observe the storage instructions on the packaging and in the instructions for use.*

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**SECTION 8: Exposure controls/personal protection**· **8.1 Control parameters**· **Ingredients with limit values that require monitoring at the workplace:**· **Additional information:**

Due to the proportions contained in relation to the amount of product during use and the way it is incorporated into the product, monitoring of specific, workplace-related limit values is not applicable.

· **8.2 Exposure controls**· **Individual protection measures, such as personal protective equipment**· **General protective and hygienic measures:**

The usual precautionary measures are to be adhered to when handling chemicals.

In the context of the use of this product, the hygiene standards customary and general in dental practice, such as hand, mouth and eye protection, must be applied.

**SECTION 9: Physical and chemical properties**· **9.1 Information on basic physical and chemical properties**· **General Information**· **Physical state**

Liquid

· **Colour:**

white to yellowish

· **Odour:**

Characteristic

· **Odour threshold:**

Not determined.

· **Melting point/freezing point:**

Undetermined.

· **Boiling point or initial boiling point and boiling range**

Undetermined.

· **Flammability**

Not applicable.

· **Lower and upper explosion limit**· **Lower:**

Not determined.

· **Upper:**

Not determined.

· **Flash point:**

Not applicable.

· **Decomposition temperature:**

Not determined.

· **pH**

Not determined.

· **Viscosity:**· **Kinematic viscosity**

Not determined.

· **Dynamic:**

Not determined.

· **Solubility**· **water:**

Not miscible or difficult to mix.

· **Partition coefficient n-octanol/water (log value)**

Not determined.

· **Vapour pressure:**

Not determined.

· **Density and/or relative density**· **Density:**

Not determined.

· **Relative density**

Not determined.

· **Vapour density**

Not determined.

· **9.2 Other information**· **Appearance:**· **Form:**

Pasty

· **Important information on protection of health and environment, and on safety.**· **Auto-ignition temperature:**

Product is not selfigniting.

· **Explosive properties:**

Product does not present an explosion hazard.

· **Change in condition**

After mixing the base and catalyst paste, the product cures according to the product description and instructions for use.

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**SECTION 10: Stability and reactivity****· 10.1 Reactivity**

After mixing the base and catalyst paste, the product cures according to the product description and instructions for use.

**· 10.2 Chemical stability** Stable.**· 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:**

Phenolic substances, especially preparations containing eugenol and thymol, lead to curing disorders. The use of zinc oxide-eugenol cements or other eugenol-containing materials in combination with this product should be avoided.

**· 10.6 Hazardous decomposition products:** No dangerous decomposition products known.**SECTION 11: Toxicological information****· Other information**

As an invasive medical device, the product is subject to relevant laws and standards which ensure the safety and performance of the product when used appropriately and in accordance with the instructions for use. Specific toxicological information is not applicable at this point. The instructions for use must be observed.

**SECTION 12: Ecological information****· General notes:**

As an invasive medical device, the product is subject to relevant laws and standards that ensure the safety and performance of the product when used properly and in accordance with the instructions for use. Special environmental information is not applicable at this point. The instructions for use must be observed.

**SECTION 13: Disposal considerations****· 13.1 Waste treatment methods****· Recommendation** Dispose of in accordance with official regulations.**· Uncleaned packaging:****· Recommendation:** Dispose of in accordance with official regulations.**SECTION 14: Transport information****· 14.1 UN number or ID number****· ADR, IMDG, IATA**

Void

**· 14.2 UN proper shipping name****· ADR, 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:**

Not applicable.

**· 14.6 Special precautions for user**

Not applicable.

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- |   |                 |
|---|-----------------|
| · <b>14.7 Maritime transport in bulk according to IMO instruments</b> | Not applicable. |
| · <b>UN "Model Regulation":</b>                                       | Void            |

**SECTION 15: Regulatory information**

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**  
Regulation (EU) 2017/745  
Medical Devices Regulation

Directive 93/42/EEC concerning medical devices

- **15.2 Chemical safety assessment:**  
The health and environmental hazards have been assessed and classified on the basis of the information known to us on the components and their reaction processes.  
A Chemical Safety Assessment has not been carried out.

**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.

The product to which this data sheet is assigned is a medical device according to the EU Medical Devices Regulation EU 2017/745. Invasive medical devices or medical devices in direct body contact are exempted from the classification and labelling requirements of Regulation (EU) 1272/2008 (AR CLP, Article 1, paragraph 5 d). The Medical Devices Regulation does not require a safety data sheet for invasive medical devices or medical devices in direct body contact, as the safe use of the product is indicated in the instructions for use and/or the labelling. Nevertheless, we provide a data sheet for medical devices in order to provide as transparent a source as possible for the assessment of hazards to humans and the environment.

- **Relevant phrases**  
H226 Flammable liquid and vapour.  
H242 Heating may cause a fire.  
H302 Harmful if swallowed.  
H314 Causes severe skin burns and eye damage.  
H315 Causes skin irritation.  
H317 May cause an allergic skin reaction.  
H319 Causes serious eye irritation.  
H331 Toxic if inhaled.  
H411 Toxic to aquatic life with long lasting effects.

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- **Version number of previous version:** 1

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**· Abbreviations and acronyms:***ADR: Accord relatif au transport international 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. 3: Flammable liquids – Category 3**Org. Perox. D: Organic peroxides – Type C/D**Acute Tox. 4: Acute toxicity – Category 4**Acute Tox. 3: Acute toxicity – Category 3**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**Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2*

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