Printing date 01.03.2018

Version number 1

Revision: 01.03.2018

Hazardous according to criteria of Australian Safety and Compensation Council.

#### **SECTION 1: Identification**

- · 1.1 Product identifier
- · Trade name: Meron Plus 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
- $\cdot$  1.3 Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:
- Australien contact and address: VOCO Australia Pty Ltd. Suite 406-408, 251 Oxford Street, Bondi Junction, NSW 2022

• Further information obtainable from: Australia 02 9369 1770

• 1.4 Emergency telephone number: Australia: 131126

## SECTION 2: Hazard(s) 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 ON SKIN: Wash with plenty of water.

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.

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 and Information on Ingredients

· 3.2 Chemical characterisation: Mixtures

• Description: Mixture of substances listed below with nonhazardous additions.

#### · Dangerous components:

fluoro-aluminosilicate glass	50-100%
<i>Eye Irrit. 2, H319</i>	
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Trade name: Meron Plus QM Base

		ttd. of page 1)
27813-02-1	hydroxypropylmethacrylate	10-25%
	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	
1830-78-0	Glycerindimethacrylate	5-10%
	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1A, H317; STOT SE 3, H335	

## **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: Fire Fighting Measures**

- · 5.1 Extinguishing media
- Suitable extinguishing agents: CO2, powder or water spray. Fight larger fire with 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
- 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.

## **SECTION 8: Exposure controls and personal protection**

• Additional information about design of technical facilities: No further data; see item 7.

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Trade name: Meron Plus QM Base

· 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

• 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:	Undetermined.	
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.	
Partition coefficient: n-octanol/water:	Not determined.	
Viscosity:		
Dynamic:	Not applicable.	

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Trade name: Meron Plus QM Base

*Kinematic:* • 9.2 Other information

*Not applicable. 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 (carcinogenity, mutagenicity and toxicity for reproduction)
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- *Reproductive toxicity Based on available data, the classification criteria are not met.*
- STOT-single exposure Based on available data, the classification criteria are not met.
- STOT-repeated exposure Based on available data, the classification criteria are not met.
- Aspiration hazard Based on available data, the classification criteria are not met.

#### **SECTION 12: Ecological Information**

· 12.1 Toxicity

- · Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- Additional ecological information:
- · General notes: Do not allow product 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.

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Trade name: Meron Plus QM Base

· Uncleaned packaging:

• Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information	tion	
14.1 UN-Number ADG, ADN, IMDG, IATA	Void	
14.2 UN proper shipping name ADG, ADN, IMDG, IATA	- Void	
14.3 Transport hazard class(es)	-	
ADG, ADN, IMDG, IATA Class	Void	
14.4 Packing group ADG, IMDG, IATA	- Void	
14.5 Environmental hazards:	Not applicable.	
14.6 Special precautions for user	Not applicable.	
14.7 Transport in bulk according to Ann Marpol and the IBC Code	<b>ex II of</b> Not applicable.	
UN "Model Regulation":	Void	

SECTION 15: Regulatory information

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

· Australian Inventory of Chemical Substances

All ingredients are listed.

· 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
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Skin Sens. 1: Skin sensitisation – Category 1
Skin Sens. 1A: Skin sensitisation – Category 1A
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

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Hazardous according to criteria of Australian Safety and Compensation Council.

#### **SECTION 1: Identification**

- · 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
- $\cdot$  1.3 Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:
- Australien contact and address: VOCO Australia Pty Ltd. Suite 406-408, 251 Oxford Street, Bondi Junction, NSW 2022

· Further information obtainable from: Australia 02 9369 1770

• 1.4 Emergency telephone number: Australia: 131126

#### **SECTION 2: Hazard(s) 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 and Information on Ingredients

· 3.2 Chemical characterisation: Mixtures

• Description: Mixture of substances listed below with nonhazardous additions.

#### · Dangerous components:

polyacrylic acid Eye Irrit. 2, H319

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10-25%

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Trade name: Meron Plus QM Catalyst

	(C	ontd. of page 1)
868-77-9	2-hydroxyethyl methacrylate	10-25%
	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	
1830-78-0	Glycerindimethacrylate Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1A, H317; STOT SE 3, H335	2.5-5%
	Katalysator	<i>≤</i> 2.5%
	Flam. Liq. 3, H226; Org. Perox. D, H242 Acute Tox. 3, H331	
	Skin Corr. 1B, H314 Acute Tox. 4, H302; Skin Sens. 1, H317	

## **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: Fire Fighting 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.
- $\cdot \textit{Further information about storage conditions: Keep container tightly sealed.}$
- 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 and 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

9.1 Information on basic physical and ch	nemical properties	
General Information		
Appearance: Form:	Director	
Form: Colour:	Pasty	
Odour:	According to product specification 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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Trade name: Meron Plus QM Catalyst

		(Contd. of page 3)
· 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.
- $\cdot$  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 (carcinogenity, mutagenicity and toxicity for reproduction)
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- Carcinogenicity Based on available data, the classification criteria are not met.
- Reproductive toxicity Based on available data, the classification criteria are not met.
- STOT-single exposure Based on available data, the classification criteria are not met.
- $\cdot \textit{STOT-repeated exposure Based on available data, the classification criteria are not met.}$
- 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.
- $\cdot$  12.6 Other adverse effects No further relevant information available.

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Trade name: Meron Plus QM Catalyst

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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**

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

## **SECTION 15: Regulatory information**

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

· Australian Inventory of Chemical Substances

All ingredients are listed.

· 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

- 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

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<sup>·</sup> 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)

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#### Trade name: Meron Plus QM Catalyst

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 Skin Sens. 1A: Skin sensitisation – Category 1A STOT SE 3: Specific target organ toxicity (single exposure) – Category 3 (Contd. of page 5)