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Version number 7

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

· 1.1 Product identifier

• Trade name: Provicol QM Plus Base

· 1.2 Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

- \cdot Application of the substance / the mixture Temporary luting cement
- · Uses advised against No further relevant information available.

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

• Further information obtainable from: Scientific department tel. +49 (0)4721-719-0

• 1.4 Emergency telephone number: Poison Control Center Mainz +49 (0)6131-19240

SECTION 2: Hazards identification

· 2.2 Label elements

· Classification according to Regulation (EC) No 1272/2008

Skin Irrit. 2 H315 Causes skin irritation.

- Eye Irrit. 2 H319 Causes serious eye irritation.
- · Labelling according to Regulation (EC) No 1272/2008
- As a medical device the product is not subject to labelling regulations under 1272/2008/EC.
- Hazard pictograms GHS07
- · Signal word Warning
- · Hazard statements
- Causes skin irritation.
- Causes serious eye irritation.
- · Precautionary statements
- Wash thoroughly after handling.
- *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 occurs: Get medical advice/attention.

Take off contaminated clothing and wash it before reuse.

- If eye irritation persists: Get medical advice/attention.
- 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:

| coconut | fatty acid | Skin Irrit. 2, H315; Eye Irrit. 2, H319 | 25-50% |
|------------------------|--------------|---|--------|
| CAS: 134-11-2 2-ethoxy | benzoic acid | Skin Irrit. 2, H315; Eye Irrit. 2, H319 | 5-10% |

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.

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- 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.
- \cdot 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 Wear protective clothing.

- 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.

No special precautions are necessary if used correctly.

Follow the instructions for use.

• Information about fire - and explosion protection: No special measures required.

· 7.2 Conditions for safe storage, including any incompatibilities

· Storage:

• Requirements to be met by storerooms and receptacles: No special requirements.

· Information about storage in one common storage facility: Not required.

• Further information about storage conditions: See storage instructions on package

•7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- · 8.1 Control parameters
- Additional information about design of technical facilities: No further data; see item 7.
- Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

• Additional information: The lists valid during the making were used as basis.

- · 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.

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^{· 8.2} Exposure controls

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Trade name: Provicol QM Plus Base

• 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.

· Penetration time of glove material

The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

• Eye protection: Safety glasses

| SECTION 9: Physical and chemical properties | | |
|--|---|--|
| • 9.1 Information on basic physical and cl • General Information • Appearance: | hemical properties | |
| Form: | Pastv | |
| Colour: | Yellow-brown | |
| · Odour: | Characteristic | |
| • Odour threshold: | Not determined. | |
| · pH-value: | Not determined. | |
| • Change in condition Melting point/freezing point: Initial boiling point and boiling range: | Undetermined. Undetermined. | |
| · Flash point: | Not applicable. | |
| · Flammability (solid, gas): | Not applicable. | |
| Decomposition temperature: | Not determined. | |
| • Auto-ignition temperature: | Product is not selfigniting. | |
| · Explosive properties: | Product does not present an explosion hazard. | |
| · Density at 20 •C: | 1.01 g/cm ³ | |
| 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.

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Trade name: Provicol QM Plus Base

- 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 Not cured:

Causes skin irritation.

- · Serious eye damage/irritation
- Causes serious eye irritation.
- Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- \cdot Additional toxicological information:
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- \cdot Carcinogenicity Based on available data, the classification criteria are not met.
- $\cdot \textit{Reproductive toxicity Based on available data, the classification criteria are not met.}$
- 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.*

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| 14 1 LINI Normal an | | |
|--|-----------------|--|
| 14.1 UN-Number ADR, ADN, IMDG, IATA | Void | |
| 14.2 UN proper shipping name | - - - | |
| ADR, ADN, IMDG, IATA | Void | |
| 14.3 Transport hazard class(es) | - | |
| ADR, ADN, IMDG, IATA | | |
| Class | Void | |
| 14.4 Packing group | _ | |
| ADR, IMDG, IATA | Void | |
| 14.5 Environmental hazards: | Not applicable. | |
| 14.6 Special precautions for user | Not applicable. | |
| 14.7 Transport in bulk according to Anna | ex 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.

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
- \cdot Abbreviations and acronyms:

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

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

· 1.1 Product identifier

· Trade name: Provicol QM Plus 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 Temporary luting cement
- Uses advised against No further relevant information available.

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

• Further information obtainable from: Scientific department tel. +49 (0)4721-719-0

· 1.4 Emergency telephone number: Poison Control Center Mainz +49 (0)6131-19240

SECTION 2: Hazards identification

· 2.2 Label elements

 \cdot Classification according to Regulation (EC) No 1272/2008

Eye Irrit. 2 H319 Causes serious eye irritation.

- · Labelling according to Regulation (EC) No 1272/2008
- As a medical device the product is not subject to labelling regulations under 1272/2008/EC.
- · Hazard pictograms GHS07
- · Signal word Warning
- Hazard statements

Causes serious eye irritation.

- · Precautionary statements
- Wash thoroughly after handling.
- Wear 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 eye irritation persists: Get medical advice/attention.

- · 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.

| Dungerous compone | 1115. | | |
|-------------------------------------|-------|--|---------------|
| CAS: 1314-13-2 EINECS: 215-222-5 | | Aquatic Acute 1, H400; Aquatic Chronic 1, H410 | 50-100% |
| CAS: 1305-62-0 EINECS: 215-137-3 | | Eye Dam. 1, H318 Skin Irrit. 2, H315; STOT SE 3, H335 | <i>≤</i> 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.

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Trade name: Provicol QM Plus Catalyst

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• 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. No special precautions are necessary if used correctly. Follow the instructions for use.

· Information about fire - and explosion protection: No special measures required.

· 7.2 Conditions for safe storage, including any incompatibilities

· Storage:

• Requirements to be met by storerooms and receptacles: No special requirements.

· Information about storage in one common storage facility: Not required.

• Further information about storage conditions: See storage instructions on package

• 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- · 8.1 Control parameters
- Additional information about design of technical facilities: No further data; see item 7.
- Ingredients with limit values that require monitoring at the workplace:
- The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Personal protective equipment:
- General protective and hygienic measures:
- The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not required.
- Protection of hands:



Protective gloves

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Trade name: Provicol QM Plus Catalyst

· Material of gloves

(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.

Penetration time of glove material

The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

• Eye protection: Safety glasses

| SECTION 9: Physical and chemical properties | | |
|---|---|--|
| •9.1 Information on basic physical and c | hemical properties | |
| · General Information | | |
| · Appearance: | | |
| Form: | Pasty | |
| Colour: | Light brown | |
| · Odour: | Characteristic | |
| • Odour threshold: | Not determined. | |
| · pH-value: | Not determined. | |
| · Change in condition | | |
| Melting point/freezing point: | Undetermined. | |
| Initial boiling point and boiling range | : Undetermined. | |
| · Flash point: | Not applicable. | |
| · Flammability (solid, gas): | Not applicable. | |
| 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 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.

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Trade name: Provicol QM Plus Catalyst

· 10.6 Hazardous decomposition products: No dangerous decomposition products known.

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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:

CAS: 1314-13-2 zinc oxide

Oral LD50 >5,000 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

· Serious eye damage/irritation

Causes serious eye irritation.

• Respiratory or skin sensitisation Based on available data, the classification criteria are not met.

 \cdot Additional toxicological information:

· CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)

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

• Carcinogenicity Based on available data, the classification criteria are not met.

• *Reproductive toxicity Based on available data, the classification criteria are not met.*

• STOT-single exposure Based on available data, the classification criteria are not met.

• STOT-repeated exposure Based on available data, the classification criteria are not met.

• Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

· 12.1 Toxicity

• Aquatic toxicity: No further relevant information available.

· 12.2 Persistence and degradability No further relevant information available.

· 12.3 Bioaccumulative potential No further relevant information available.

· 12.4 Mobility in soil No further relevant information available.

Additional ecological information:

· General notes: 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.

· Uncleaned packaging:

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

| · 14.1 UN-Number | - | |
|--------------------------------|------|--|
| · ADR, ADN, IMDG, IATA | Void | |
| · 14.2 UN proper shipping name | _ | |

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| | | (Contd. of page 4 |
|--|------------------------------------|-------------------|
| · ADR, ADN, IMDG, IATA | Void | |
| · 14.3 Transport hazard class(es) | - | |
| · ADR, ADN, IMDG, IATA · Class | Void | |
| | voiu | |
| · 14.4 Packing group · ADR, 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 | ex 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

· Directive 2012/18/EU

· Named dangerous substances - ANNEX I None of the ingredients is listed.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· Department issuing SDS: Scientific department

• Contact: Tel.: +49 (0)4721-719-0

Abbreviations and acronyms:

Skin Irrit. 2: Skin corrosion/irritation – Category 2 Eye Dam. 1: Serious eye damage/eye irritation – Category 1 Eye Irrit. 2: Serious eye damage/eye irritation – Category 2 STOT SE 3: Specific target organ toxicity (single exposure) – Category 3 Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1