Printing date 05.01.2017

Version number 10

Revision: 05.01.2017

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

· 1.1 Product identifier

· Trade name: Provicol/SC 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
- $\cdot$  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

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

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

- · 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.
- · 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.

- IF ON SKIN: Wash with plenty of soap and water.
- · 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

319 25-50%

#### **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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- 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
- See Section 7 for information on safe handling.
- See Section 8 for information on personal protection equipment.
- See Section 13 for disposal information.

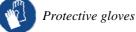
#### **SECTION 7: Handling and storage**

- · 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:
- The usual precautionary measures are to be adhered to when handling chemicals. Avoid contact with the eyes and skin.
- · Protection of hands:



# · 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

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(Contd. of page 2) 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 physic • General Information	cal and chemical properties
· Appearance:	
Form:	Pasty
Colour:	Yellow-brown
· Odour:	Characteristic
· pH-value:	Not determined.
· Change in condition	
Melting point/Melting range:	
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 Causes skin irritation.
- $\cdot$  Serious eye damage/irritation
- Causes serious eye irritation.
- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · 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.

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- Reproductive toxicity Based on available data, the classification criteria are not met.
- $\cdot \textit{STOT-single exposure Based on available data, the classification criteria are not met.}$
- 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: Generally not hazardous for water
- · 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 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 Ann. Marpol and the IBC Code	<b>ex II of</b> Not applicable.	
- UN ''Model Regulation'':	Void	

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Trade name: Provicol/SC base

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#### **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* 

• \* Data compared to the previous version altered.

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Revision: 04.01.2017

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

· 1.1 Product identifier

· Trade name: Provicol/SC 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
- $\cdot$  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.

- · 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.

· 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.

IF ON SKIN: Wash with plenty of soap and water.

- · 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:			
		10-25%	
EINECS: 215-222-5	Aquatic Acute 1, H400; Aquatic Chronic 1, H410		
	calcium dihydroxide	2.5-5%	
EINECS: 215-137-3	Eye Dam. 1, H318		
	Skin Irrit. 2, H315; STOT SE 3, H335		
	oleic acid, pure	≤ 2.5%	
EINECS: 204-007-1	Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335		

#### **SECTION 4: First aid measures**

· 4.1 Description of first aid measures

· After inhalation: Seek medical treatment in case of complaints.

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Trade name: Provicol/SC catalyst

- 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 No dangerous substances are released.

# **SECTION 7: Handling and storage**

· 7.1 Precautions for safe handling

For dental use only.

No special measures required.

- · 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:
- $\cdot$  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/SC catalyst

#### · Material of gloves

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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:	Cream coloured			
· Odour:	Characteristic			
· pH-value:	Not determined.			
· Change in condition				
Melting point/Melting range:	ting 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.			
<ul> <li>9.2 Other information</li> </ul>	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:

1314-13-2 zinc oxide

 $Oral \ LD50 > 5000 \ mg/kg \ (rat)$ 

• Primary irritant effect:

· Skin corrosion/irritation

Testing according to ISO 10993-1/10993-10 showed no skin irritation for this product when fully cured

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Trade name: Provicol/SC catalyst

- · Serious eye damage/irritation
- Causes serious eye irritation.
- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · 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.
- $\cdot$  **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.

### **SECTION 14: Transport information**

· 14.1 UN-Number · ADR, IMDG, IATA	Void	
· 14.2 UN proper shipping name · ADR, IMDG, IATA	Void	
· 14.3 Transport hazard class(es)		
· ADR, 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 Ann Marpol and the IBC Code	ex II of Not applicable.	

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#### **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)
- LC50: Lethal concentration, 50 percent
- LD50: Lethal dose, 50 percent
- PBT: Persistent, Bioaccumulative and Toxic
- vPvB: very Persistent and very Bioaccumulative 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

 $\cdot$  \* Data compared to the previous version altered.