Printing date 01/05/2017 Reviewed on 01/05/2017

1 Identification

- · Product identifier
- · Trade name: Provicol/SC base
- · Application of the substance / the mixture Temporary luting cement
- · Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

VOCO GmbH

Anton-Flettner-Str. 1-3 D-27472 Cuxhaven

- · Information department: Scientific department tel. +49 (0)4721-719-0
- · Emergency telephone number: Scientific department tel. +49 (0)4721-719-0

2 Hazard(s) identification

· Classification of the substance or mixture



Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2B H320 Causes eye irritation.

- · Label elements
- · Hazard pictograms GHS07
- · Signal word Warning
- · Hazard statements

Causes skin and 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.

- · Other hazards Use only for intended scope of application
- · Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.

3 Composition/information on ingredients

- · Chemical characterization: Mixtures
- · Description: Mixture of the substances listed below with nonhazardous additions.
- · Dangerous components:

coconut fatty acid

Skin Irrit. 2, H315; Eye Irrit. 2A, H319

25-50%

4 First-aid measures

- · 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.
- · Information for doctor:
- · Most important symptoms and effects, both acute and delayed No further relevant information available.

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Trade name: Provicol/SC base

(Contd. of page 1)

· Indication of any immediate medical attention and special treatment needed No further relevant information available.

5 Fire-fighting measures

- · Extinguishing media
- · Suitable extinguishing agents:

CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

- · Special hazards arising from the substance or mixture No further relevant information available.
- · Advice for firefighters
- · Protective equipment: No special measures required.

6 Accidental release measures

- · Personal precautions, protective equipment and emergency procedures Not required.
- · Environmental precautions: No special measures required.
- · Methods and material for containment and cleaning up: Pick up mechanically.
- · 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.

7 Handling and storage

- · Handling:
- · Precautions for safe handling For dental use only.
- · Information about protection against explosions and fires: No special measures required.
- · 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
- · Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

- · Additional information about design of technical systems: No further data; see item 7.
- · Control parameters
- · Components 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 that were valid during the creation were used as basis.
- · Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures:

The usual precautionary measures for handling chemicals should be followed.

Avoid contact with the eyes and skin.

· Protection of hands:



Protective gloves

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the (Contd. on page 3)

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Trade name: Provicol/SC base

(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

9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

· Appearance:

Form: Pasty
Color: Yellow-brown
Odor: Characteristic

· pH-value: Not determined.

· Change in condition

Melting point/Melting range: Undetermined. Boiling point/Boiling range: Undetermined.

· Flash point: Not applicable.

· Auto 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.

• *Other information* No further relevant information available.

10 Stability and reactivity

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

11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity:
- · Primary irritant effect:
- · on the skin:

Testing according to ISO 10993-1/10993-10 showed no skin irritation for this product when fully cured Irritant to skin and mucous membranes.

- · on the eye: Strong irritant with the danger of severe eye injury.
- · Sensitization: No sensitizing effects known.
- · Additional toxicological information:

The product shows the following dangers according to internally approved calculation methods for preparations:

(Contd. on page 4)

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Trade name: Provicol/SC base

(Contd. of page 3)

Irritant

- · Carcinogenic categories
- · IARC (International Agency for Research on Cancer)

The component 64-17-5 Ethanol is listed by IARC as Group 1 but in alcoholic beverages consumption only. This product is not an alcoholic beverage.

This product is not an alcoholic core age.				
	fumed silica	3		
102-71-6	5 2,2',2"-nitrilotriethanol	3		
64-17-5	ethanol	1		
· NTP (National Toxicology Program)				
None of the ingredients is listed.				
· OSHA-Ca (Occupational Safety & Health Administration)				
None of the ingredients is listed				

12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behavior in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes: Generally not hazardous for water
- · Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- · Other adverse effects No further relevant information available.

13 Disposal considerations

- · Waste treatment methods
- · Recommendation:

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packagings:
- · Recommendation: Disposal must be made according to official regulations.

· UN-Number		
· DOT, ADR, ADN, IMDG, IATA	Void	
UN proper shipping name		
DOT, ADR, ADN, IMDG, IATA	Void	
Transport hazard class(es)		
DOT, ADR, ADN, IMDG, IATA		
Class	Void	
Packing group		
DOT, ADR, IMDG, IATA	Void	
· Environmental hazards:		
· Marine pollutant:	No	

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Trade name: Provicol/SC base

(Contd. of page 4)

· Special precautions for user Not applicable.

· Transport in bulk according to Annex II of

MARPOL73/78 and the IBC Code Not applicable.

· UN "Model Regulation": Void

15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Sara
- · Section 355 (extremely hazardous substances):

None of the ingredients are listed.

· Section 313 (Specific toxic chemical listings):

None of the ingredients are listed.

· TSCA (Toxic Substances Control Act):

All ingredients are listed.

- · Proposition 65
- · Chemicals known to cause cancer:

None of the ingredients are listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients are listed

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients are listed

· Chemicals known to cause developmental toxicity:

64-17-5 ethanol

- · Cancerogenity categories
- · EPA (Environmental Protection Agency)

None of the ingredients are listed

· TLV (Threshold Limit Value established by ACGIH)

64-17-5 ethanol

A3

· NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients are listed

· GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

- · Hazard pictograms GHS07
- · Signal word Warning
- · Hazard statements

Causes skin and 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.

16 Other information

· Department issuing SDS: Scientific department

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Safety Data Sheet acc. to OSHA HCS

Printing date 01/05/2017 Reviewed on 01/05/2017

Trade name: Provicol/SC base

· Contact: Tel.: +49 (0)4721-719-0

• Contact. 1et.. +49 (0)4721-719-0
• Date of preparation / last revision 01/05/2017 / 9

· 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

DOT: US Department of Transportation IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

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 NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit REL: Recommended Exposure Limit

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2A: Serious eye damage/eye irritation - Category 2A

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

 \cdot * Data compared to the previous version altered.

HS

Printing date 01/04/2017 Reviewed on 01/04/2017

1 Identification

- · Product identifier
- · Trade name: Provicol/SC catalyst
- · Application of the substance / the mixture Temporary luting cement
- · Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

VOCO GmbH

Anton-Flettner-Str. 1-3 D-27472 Cuxhaven

- · Information department: Scientific department tel. +49 (0)4721-719-0
- · Emergency telephone number: Scientific department tel. +49 (0)4721-719-0

2 Hazard(s) identification

Health effects are based on the unmixed/uncured material.

Under FDA regulations this product is classified as a medical device.

Medical devices are exempt from the labelling provisions of GHS according to the Hazard Communication Standard (HCS).

· Classification of the substance or mixture



Eye Irrit. 2A H319 Causes serious eye irritation.

- · Label elements
- · Hazard pictograms GHS07
- · Signal word Warning
- · 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.

- · Other hazards Use only for intended scope of application
- · Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.

3 Composition/information on ingredients

- · Chemical characterization: Mixtures
- · Description: Mixture of the substances listed below with nonhazardous additions.

Γ	· Dangerous components:				
	1305-62-0	calcium dihydroxide	Eye Dam. 1, H318 Skin Irrit. 2, H315; STOT SE 3, H335	2.5-5%	
ſ	112-80-1	oleic acid, pure	Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335	≤ 2.5%	

4 First-aid measures

- · 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.

(Contd. on page 2)

Printing date 01/04/2017 Reviewed on 01/04/2017

Trade name: Provicol/SC catalyst

(Contd. of page 1)

· 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.
- · Information for doctor:
- · Most important symptoms and effects, both acute and delayed No further relevant information available.
- · Indication of any immediate medical attention and special treatment needed No further relevant information available.

5 Fire-fighting measures

- · Extinguishing media
- $\cdot \textit{Suitable extinguishing agents: } \textit{Use fire fighting measures that suit the environment.}$
- · Special hazards arising from the substance or mixture No further relevant information available.
- · Advice for firefighters
- · Protective equipment: No special measures required.

6 Accidental release measures

- · Personal precautions, protective equipment and emergency procedures Not required.
- Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · Methods and material for containment and cleaning up: Pick up mechanically.
- · Reference to other sections No dangerous substances are released.

7 Handling and storage

- · Handling:
- · Precautions for safe handling

For dental use only.

No special measures required.

- · Information about protection against explosions and fires: No special measures required.
- · 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
- · Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

- · Additional information about design of technical systems: No further data; see item 7.
- · Control parameters
- · Components 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 that were valid during the creation were used as basis.
- · Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures:

The usual precautionary measures for handling chemicals should be followed.

· Breathing equipment: Not required.

(Contd. on page 3)

(Contd. of page 2)

Safety Data Sheet acc. to OSHA HCS

Printing date 01/04/2017 Reviewed on 01/04/2017

Trade name: Provicol/SC catalyst

· 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 Physical and chemical properties

- · Information on basic physical and chemical properties
- · General Information
- · Appearance:

Form: Pasty

Color: Cream colored
Odor: Characteristic

pH-value: Not determined.

· Change in condition

Melting point/Melting range: Undetermined. Boiling point/Boiling range: Undetermined.

· Flash point: Not applicable.

· Auto 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.

• Other information No further relevant information available.

10 Stability and reactivity

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

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Printing date 01/04/2017 Reviewed on 01/04/2017

Trade name: Provicol/SC catalyst

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11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity:
- · LD/LC50 values that are relevant for classification:

1314-13-2 zinc oxide

Oral LD50 > 5000 mg/kg (rat)

- · Primary irritant effect:
- · on the skin:

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

- · on the eye: Irritating effect.
- · Sensitization: No sensitizing effects known.
- · Additional toxicological information:

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

- · Carcinogenic categories
- · IARC (International Agency for Research on Cancer)

None of the ingredients is listed

· NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behavior in environmental systems:
- $\cdot \textbf{\it Bioaccumulative potential} \ No \ further \ relevant \ information \ available.$
- · 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.
- · Results of PBT and vPvB assessment
- · **PBT**: Not applicable.
- · vPvB: Not applicable.
- · Other adverse effects No further relevant information available.

13 Disposal considerations

- · Waste treatment methods
- · Recommendation:

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packagings:
- · Recommendation: Disposal must be made according to official regulations.

14 Transport information

- · UN-Number
- · ADR, IMDG, IATA

Void

(Contd. on page 5)

Printing date 01/04/2017 Reviewed on 01/04/2017

Trade name: Provicol/SC catalyst

		(Contd. of page 4)
· UN proper shipping name · ADR, IMDG, IATA	Void	
· Transport hazard class(es)		
· ADR, IMDG, IATA · Class	Void	
· Packing group · ADR, IMDG, IATA	Void	
· Environmental hazards: · Marine pollutant:	Not applicable. Yes (DOT)	
· Special precautions for user	Not applicable.	
· Transport in bulk according to Annex I MARPOL73/78 and the IBC Code	I of Not applicable.	

15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Sara
- · Section 355 (extremely hazardous substances):

None of the ingredients are listed.

· Section 313 (Specific toxic chemical listings):

1314-13-2 zinc oxide

- · TSCA (Toxic Substances Control Act):
- All ingredients are listed.
- · Proposition 65
- · Chemicals known to cause cancer:

None of the ingredients are listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients are listed

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients are listed

· Chemicals known to cause developmental toxicity:

None of the ingredients are listed

· Cancerogenity categories

· EPA (Environmental Protection Agency)

1314-13-2 zinc oxide

D, I, II

· TLV (Threshold Limit Value established by ACGIH)

1309-48-4 magnesium oxide

A4

· NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients are listed

· GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

- · Hazard pictograms GHS07
- · Signal word Warning
- · Hazard statements

Causes serious eye irritation.

· Precautionary statements

Wear protective gloves / eye protection.

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Printing date 01/04/2017 Reviewed on 01/04/2017

Trade name: Provicol/SC catalyst

(Contd. of page 5)

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.

16 Other information

The information contained herein is based on our present knowledge and is believed to be correct at the date issued. The information is subject to change without notice. However, all information, statements, recommendations or suggestions shall not constitute any guarantee, representation or warranty, expressed or implied.

Final determination whether the product is fit and suitable for a particular purpose and the user's method of use or application is the sole responsibility of the user.

- · Department issuing SDS: Scientific department
- · Contact: Tel.: +49 (0)4721-719-0
- · Date of preparation / last revision 01/04/2017 / 8
- · 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

ACGIH: American Conference of Governmental Industrial Hygienists

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

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Skin Irrit. 2: Skin corrosion/irritation – Category 2

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

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

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

* * Data compared to the previous version altered.

US