Data sheet for medical devices / EU

Printing date 03.07.2024 Version number 2 (replaces version 1) Revision: 03.07.2024

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

· **1.1 Product identifier**

· **Trade name: Provicol base**
· **Chemical Identification:**
This product is a medical device according to Directive 93/42/EEC concerning medical devices or Regulation (EU) 2017/745 (MDR), which is used invasively or in contact with the body. Therefore, it is exempt from the classification and labelling requirements of Regulation (EC) 1272/2008 (AR CLP, Article 1, paragraph 5 d).
A safety data sheet is not required by law for this product. This information is provided on a voluntary basis in the form of this Medical Devices Data Sheet.
· **Product category** Dental medical device
· **Article category**
The information relevant for the application and for the safety of users and patients is defined in the product-specific directions for use.The instructions for use must be observed.
Use of the product only by personnel trained in dentistry.
· **Application of the substance / the mixture**
Temporary cement for the attachment and for sealing of small one-surface cavities.

· **1.3 Details of the supplier of the data sheet**
· **Manufacturer/Supplier:**
VOCO GmbH
Anton-Flettner-Str. 1-3
D-27472 Cuxhaven
info@voco.de
+49 (0) 4721-719-0 Mo - Fr / 08:00h - 16:00h

SECTION 2: Hazards identification

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

Skin Irrit. 2 H315 Causes skin irritation.

Eye Dam. 1 H318 Causes serious eye damage.

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

· **2.3 Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· **3.2 Mixtures**
· **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**		
modyfied colophony	Skin Sens. 1, H317	50-75%
Coconut fatty acid	Eye Dam. 1, H318; Skin Irrit. 2, H315	25-50%

· **Additional information:**
Further information on ingredients can be found in the instructions for use.
In case of known hypersensitivity to the ingredients mentioned in the instructions for use, do not use the product.

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Data sheet for medical devices / EU

Trade name: Provicol base

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SECTION 4: First aid measures

· **4.1 Description of first aid measures**
· **General information:** No special measures required.
· **After inhalation:** Supply fresh air; consult doctor in case of complaints.
· **After skin contact:** Generally the product does not irritate the skin.
· **After eye contact:** Rinse opened eye for several minutes under running water.
· **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 In case of contact with mucous membranes during treatment:** No special measures required.

SECTION 5: Firefighting measures

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

SECTION 6: Accidental release measures

· **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
· **6.2 Environmental precautions:** No special measures required.
· **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.
· **6.4 Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

· **7.1 Precautions for safe handling**
No special precautions are necessary if used correctly.
For use in dental application only.
Observe the instructions for use! This contains the relevant application and safety information for the use of this product.
· **Information about fire - and explosion protection:** No special measures required.

· **7.2 Conditions for safe storage, including any incompatibilities**
· **Storage:**
· **Requirements to be met by storerooms and receptacles:** No special requirements.
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:**
Please observe the storage instructions on the packaging and in the instructions for use.

SECTION 8: Exposure controls/personal protection

· **8.1 Control parameters**
· **Ingredients with limit values that require monitoring at the workplace:**
· **Additional information:**
Due to the proportions contained in relation to the amount of product during use and the way it is incorporated into the product, monitoring of specific, workplace-related limit values is not applicable.

· **8.2 Exposure controls**
· **Individual protection measures, such as personal protective equipment**
· **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.

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Data sheet for medical devices / EU

Trade name: Provicol base

(Contd. of page 2)

Wash hands before breaks and at the end of work.
In the context of the use of this product, the hygiene standards customary and general in dental practice, such as hand, mouth and eye protection, must be applied.

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**	
· **General Information**	
· **Physical state**	Fluid
· **Colour:**	Yellow-brown
· **Odour:**	Characteristic
· **Odour threshold:**	Not determined.
· **Melting point/freezing point:**	Undetermined.
· **Boiling point or initial boiling point and boiling range**	Undetermined.
· **Flammability**	Not applicable.
· **Lower and upper explosion limit**	
· **Lower:**	Not determined.
· **Upper:**	Not determined.
· **Flash point:**	Not applicable.
· **Decomposition temperature:**	Not determined.
· **pH**	Not determined.
· **Viscosity:**	
· **Kinematic viscosity**	Not determined.
· **Dynamic:**	Not determined.
· **Solubility**	
· **water:**	Not miscible or difficult to mix.
· **Partition coefficient n-octanol/water (log value)**	Not determined.
· **Vapour pressure:**	Not determined.
· **Density and/or relative density**	
· **Density:**	Not determined.
· **Relative density**	Not determined.
· **Vapour density**	Not determined.

· **9.2 Other information**	
· **Appearance:**	
· **Form:**	Pasty
· **Important information on protection of health and environment, and on safety.**	
· **Auto-ignition temperature:**	Product is not selfigniting.
· **Explosive properties:**	Product does not present an explosion hazard.
· **Change in condition**	After mixing the base and catalyst paste, the product cures according to the product description and instructions for use.

SECTION 10: Stability and reactivity

· **10.1 Reactivity**
After mixing the base and catalyst paste, the product cures according to the product description and instructions for use.
· **10.2 Chemical stability** Stable.
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **10.3 Possibility of hazardous reactions** No dangerous reactions known.
· **10.4 Conditions to avoid** No further relevant information available.
· **10.5 Incompatible materials:** No further relevant information available.

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Trade name: Provicol base

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

SECTION 11: Toxicological information

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

SECTION 12: Ecological information

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

SECTION 13: Disposal considerations

· **13.1 Waste treatment methods**
· **Recommendation** Dispose of in accordance with official regulations.

· **Uncleaned packaging:**
· **Recommendation:** Dispose of in accordance with official regulations.

SECTION 14: Transport information

· **14.1 UN number or ID number**	
· **ADR, IMDG, IATA**	Void
· **14.2 UN proper shipping name**	
· **ADR, IMDG, IATA**	Void
· **14.3 Transport hazard class(es)**	
· **ADR, ADN, IMDG, IATA**	
· **Class**	Void
· **14.4 Packing group**	
· **ADR, IMDG, IATA**	Void
· **14.5 Environmental hazards:**	Not applicable.
· **14.6 Special precautions for user**	Not applicable.
· **14.7 Maritime transport in bulk according to IMO instruments**	Not applicable.
· **UN "Model Regulation":**	Void

SECTION 15: Regulatory information

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

Directive 93/42/EEC concerning medical devices
· **15.2 Chemical safety assessment:**
The health and environmental hazards have been assessed and classified on the basis of the information known to us on the components and their reaction processes.

(Contd. on page 5)

Data sheet for medical devices / EU

Trade name: Provicol base

(Contd. of page 4)

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.
The product to which this data sheet is assigned is a medical device according to the EU Medical Devices Regulation EU 2017/745. Invasive medical devices or medical devices in direct body contact are exempted from the classification and labelling requirements of Regulation (EU) 1272/2008 (AR CLP, Article 1, paragraph 5 d). The Medical Devices Regulation does not require a safety data sheet for invasive medical devices or medical devices in direct body contact, as the safe use of the product is indicated in the instructions for use and/or the labelling. Nevertheless, we provide a data sheet for medical devices in order to provide as transparent a source as possible for the assessment of hazards to humans and the environment.

· **Relevant phrases**
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.

· **Department issuing Datasheet:** *Scientific department*
· **Contact:**
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Level 19, 133-145 Castlereagh Street
Sydney, NSW 2000
Email: info@voco.com

For further contact information, please visit www.voco.dental
· **Version number of previous version:** *1*
· **Abbreviations and acronyms:**
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
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 Dam. 1: Serious eye damage/eye irritation – Category 1
Skin Sens. 1: Skin sensitisation – Category 1

Data sheet for medical devices / EU

Printing date 03.07.2024 Version number 2 (replaces version 1) Revision: 03.07.2024

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

· **1.1 Product identifier**

· **Trade name: Provicol catalyst**
· **Chemical Identification:**
This product is a medical device according to Directive 93/42/EEC concerning medical devices or Regulation (EU) 2017/745 (MDR), which is used invasively or in contact with the body. Therefore, it is exempt from the classification and labelling requirements of Regulation (EC) 1272/2008 (AR CLP, Article 1, paragraph 5 d).
A safety data sheet is not required by law for this product. This information is provided on a voluntary basis in the form of this Medical Devices Data Sheet.
· **Product category** Dental medical device
· **Article category**
The information relevant for the application and for the safety of users and patients is defined in the product-specific directions for use.The instructions for use must be observed.
Use of the product only by personnel trained in dentistry.
· **Application of the substance / the mixture**
Temporary cement for the attachment and for sealing of small one-surface cavities.

· **1.3 Details of the supplier of the data sheet**
· **Manufacturer/Supplier:**
VOCO GmbH
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D-27472 Cuxhaven
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SECTION 2: Hazards identification

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

Eye Dam. 1 H318 Causes serious eye damage.
· **2.3 Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· **3.2 Mixtures**
· **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**		
zinc oxide	Aquatic Acute 1, H400; Aquatic Chronic 1, H410	10-25%
calcium dihydroxide	Eye Dam. 1, H318; Skin Irrit. 2, H315; STOT SE 3, H335	2.5-10%
oleic acid, pure	Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	0.1-1%

· **Additional information:**
Further information on ingredients can be found in the instructions for use.
In case of known hypersensitivity to the ingredients mentioned in the instructions for use, do not use the product.

(Contd. on page 2)

Data sheet for medical devices / EU

Trade name: Provicol catalyst

(Contd. of page 1)

SECTION 4: First aid measures

· **4.1 Description of first aid measures**
· **General information:** No special measures required.
· **After inhalation:** Supply fresh air; consult doctor in case of complaints.
· **After skin contact:** Generally the product does not irritate the skin.
· **After eye contact:** Rinse opened eye for several minutes under running water.
· **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 In case of contact with mucous membranes during treatment:** No special measures required.

SECTION 5: Firefighting measures

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

SECTION 6: Accidental release measures

· **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
· **6.2 Environmental precautions:**
Inform respective authorities in case of seepage into water course or sewage system.
No special measures required.
· **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
· **6.4 Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

· **7.1 Precautions for safe handling**
No special precautions are necessary if used correctly.
For use in dental application only.
Observe the instructions for use! This contains the relevant application and safety information for the use of this product.
· **Information about fire - and explosion protection:** No special measures required.

· **7.2 Conditions for safe storage, including any incompatibilities**
· **Storage:**
· **Requirements to be met by storerooms and receptacles:** No special requirements.
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:**
Please observe the storage instructions on the packaging and in the instructions for use.

SECTION 8: Exposure controls/personal protection

· **8.1 Control parameters**
· **Ingredients with limit values that require monitoring at the workplace:**
· **Additional information:**
Due to the proportions contained in relation to the amount of product during use and the way it is incorporated into the product, monitoring of specific, workplace-related limit values is not applicable.

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Data sheet for medical devices / EU

Trade name: Provicol catalyst

(Contd. of page 2)

· **8.2 Exposure controls**
· **Individual protection measures, such as personal protective equipment**
· **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
Wash hands before breaks and at the end of work.
In the context of the use of this product, the hygiene standards customary and general in dental practice, such as hand, mouth and eye protection, must be applied.

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**
· **General Information**

· **Physical state**	pasty
· **Colour:**	Cream coloured
· **Odour:**	Characteristic
· **Odour threshold:**	Not determined.
· **Melting point/freezing point:**	Undetermined.
· **Boiling point or initial boiling point and boiling range**	Undetermined.
· **Flammability**	Not applicable.
· **Lower and upper explosion limit**	
· **Lower:**	Not determined.
· **Upper:**	Not determined.
· **Flash point:**	Not applicable.
· **Decomposition temperature:**	Not determined.
· **pH**	Not determined.
· **Viscosity:**	
· **Kinematic viscosity**	Not determined.
· **Dynamic:**	Not determined.
· **Solubility**	
· **water:**	Not miscible or difficult to mix.
· **Partition coefficient n-octanol/water (log value)**	Not determined.
· **Vapour pressure:**	Not determined.
· **Density and/or relative density**	
· **Density:**	Not determined.
· **Relative density**	Not determined.
· **Vapour density**	Not determined.

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

· **Form:**	Pasty
· **Important information on protection of health and environment, and on safety.**	
· **Auto-ignition temperature:**	Product is not selfigniting.
· **Explosive properties:**	Product does not present an explosion hazard.
· **Change in condition**	After mixing the base and catalyst paste, the product cures according to the product description and instructions for use.

SECTION 10: Stability and reactivity

· **10.1 Reactivity**
After mixing the base and catalyst paste, the product cures according to the product description and instructions for use.
· **10.2 Chemical stability** Stable.
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **10.3 Possibility of hazardous reactions** No dangerous reactions known.

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Data sheet for medical devices / EU

Trade name: Provicol catalyst

(Contd. of page 3)

· **10.4 Conditions to avoid** No further relevant information available.
· **10.5 Incompatible materials:** No further relevant information available.
· **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

SECTION 11: Toxicological information

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

SECTION 12: Ecological information

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

SECTION 13: Disposal considerations

· **13.1 Waste treatment methods**
· **Recommendation** Dispose of in accordance with official regulations.

· **Uncleaned packaging:**
· **Recommendation:** Dispose of in accordance with official regulations.

SECTION 14: Transport information

· **14.1 UN number or ID number**	
· **ADR, IMDG, IATA**	Void
· **14.2 UN proper shipping name**	
· **ADR, IMDG, IATA**	Void
· **14.3 Transport hazard class(es)**	
· **ADR, ADN, IMDG, IATA**	
· **Class**	Void
· **14.4 Packing group**	
· **ADR, IMDG, IATA**	Void
· **14.5 Environmental hazards:**	Not applicable.
· **14.6 Special precautions for user**	Not applicable.
· **14.7 Maritime transport in bulk according to IMO instruments**	Not applicable.
· **UN "Model Regulation":**	Void

SECTION 15: Regulatory information

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

Directive 93/42/EEC concerning medical devices

(Contd. on page 5)

Data sheet for medical devices / EU

Trade name: Provicol catalyst

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

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.
The product to which this data sheet is assigned is a medical device according to the EU Medical Devices Regulation EU 2017/745. Invasive medical devices or medical devices in direct body contact are exempted from the classification and labelling requirements of Regulation (EU) 1272/2008 (AR CLP, Article 1, paragraph 5 d). The Medical Devices Regulation does not require a safety data sheet for invasive medical devices or medical devices in direct body contact, as the safe use of the product is indicated in the instructions for use and/or the labelling. Nevertheless, we provide a data sheet for medical devices in order to provide as transparent a source as possible for the assessment of hazards to humans and the environment.

· **Relevant phrases**
H315 Causes skin irritation.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

· **Department issuing Datasheet:** Scientific department
· **Contact:**
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· **Version number of previous version:** 1
· **Abbreviations and acronyms:**
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
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 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