Data sheet for medical devices / GB

Printing date 06.11.2023 Version number 1 Revision: 03.11.2023

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

· **1.1 Product identifier**

· **Trade name: Rebilda DC 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 GB 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** Core-build up material

· **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 GB 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 Sens. 1 H317 May cause an allergic skin reaction.

Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.

· **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:**	
UDMA Aquatic Chronic 2, H411; Skin Sens. 1, H317	10-25%
DDDMA Aquatic Acute 1, H400; Aquatic Chronic 1, H410; Skin Sens. 1B, H317	2.5-10%
HEDMA Aquatic Chronic 3, H412	2.5-10%
2,2'-[(4-methylphenyl)imino]bisethanol Eye Dam. 1, H318; Acute Tox. 4, H302; Skin Sens. 1, H317; Aquatic Chronic 3, H412	0.1-1%

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Data sheet for medical devices / GB

Trade name: Rebilda DC base

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· ***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.

SECTION 4: First aid measures

· ***4.1 Description of first aid measures***
· ***General information:*** *No special measures required.*
· ***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.*
· ***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:*** *Remove excess immediately.*

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.

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Data sheet for medical devices / GB

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SECTION 8: Exposure controls/personal protection

· **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:**
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.
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:**	According to product specification
· **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.

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Data sheet for medical devices / GB

Trade name: Rebilda DC base

(Contd. of page 3)

· **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. The material will cure if exposed to light. Follow the instructions for light curing in the 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.
The material will cure if exposed to light.
· **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:**
Phenolic substances, especially preparations containing eugenol and thymol, lead to curing disorders.The use of zinc oxide-eugenol cements or other eugenol-containing materials in combination with this product should be avoided.
· **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

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Data sheet for medical devices / GB

Trade name: Rebilda DC base

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· **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.
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 GB 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.

· **Department issuing Datasheet:** Knowledge Communication Department
· **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
Acute Tox. 4: Acute toxicity – Category 4
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Skin Sens. 1: Skin sensitisation – Category 1
Skin Sens. 1B: Skin sensitisation – Category 1B
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
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

Data sheet for medical devices / GB

Printing date 06.11.2023 Version number 1 Revision: 03.11.2023

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

· **1.1 Product identifier**

· **Trade name: Rebilda DC 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 GB 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** Core-build up material

· **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 GB 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 Sens. 1 H317 May cause an allergic skin reaction.

Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.

· **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:**	
UDMA Aquatic Chronic 2, H411; Skin Sens. 1, H317	10-25%
HEDMA Aquatic Chronic 3, H412	2.5-10%
DDDMA Aquatic Acute 1, H400; Aquatic Chronic 1, H410; Skin Sens. 1B, H317	2.5-10%
benzoyl peroxide Org. Perox. C, H242; Aquatic Acute 1, H400; Aquatic Chronic 1, H410; Eye Irrit. 2, H319; Skin Sens. 1, H317	0.1-1%

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Data sheet for medical devices / GB

Trade name: Rebilda DC catalyst

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· ***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.

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:*** *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 In case of contact with mucous membranes during treatment:*** *Remove excess immediately.*

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:*** *No special measures required.*
· ***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 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:***
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

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Data sheet for medical devices / GB

Trade name: Rebilda DC catalyst

(Contd. of page 2)

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

· **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. The material will cure if exposed to light.

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.

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Data sheet for medical devices / GB

Trade name: Rebilda DC catalyst

(Contd. of page 3)

The material will cure if exposed to light.
· **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.
· **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.
· **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

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

(Contd. on page 5)

Data sheet for medical devices / GB

Trade name: Rebilda DC catalyst

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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.
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 GB 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.

· **Department issuing Datasheet:** Knowledge Communication Department
· **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
Org. Perox. C: Organic peroxides – Type C/D
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Skin Sens. 1: Skin sensitisation – Category 1
Skin Sens. 1B: Skin sensitisation – Category 1B
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
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

Data sheet for medical devices / EU

Printing date 20.08.2024 Version number 1 Revision: 19.07.2024

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

· **1.1 Product identifier**

· **Trade name: Rebilda Post/GT**
· **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.
The product should only be applied by a professionally trained dental practitioner.
· **Application of the substance / the mixture** Root canal post

· **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:
The substance is not classified, according to the CLP regulation.

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

SECTION 3: Composition/information on ingredients

· **Additional information:** Solid composite of glass fibers, inorganic fillers and polydimethacrylates.

SECTION 4: First aid measures

· **4.1 Description of first aid measures**
· **General information:** No special measures required.
· **After skin contact:** Generally the product does not irritate the skin.
· **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.
Rinse out mouth and then drink plenty of water.
· **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.

(Contd. on page 2)

Data sheet for medical devices / EU

Trade name: Rebilda Post/GT

(Contd. of page 1)

· **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:** Not required.
· **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.
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.

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Data sheet for medical devices / EU

Trade name: Rebilda Post/GT

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SECTION 9: Physical and chemical properties

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

· **9.2 Other information**	
· **Appearance:**	
· **Form:**	Solid
· **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**	Not applicable.

SECTION 10: Stability and reactivity

· **10.1 Reactivity** No further relevant information available.
· **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.
· **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.

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Data sheet for medical devices / EU

Trade name: Rebilda Post/GT

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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. For further information, see the instructions for use.

· **Uncleaned packaging:**
· **Recommendation:** Disposal must be made according to 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.
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

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Data sheet for medical devices / EU

Trade name: Rebilda Post/GT

(Contd. of page 4)

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.

· ***Department issuing Datasheet:*** *Knowledge Communication Department*
· ***Contact:***
Global headquarter:
VOCO GmbH
Anton-Flettner-Str. 1-3
D-27472 Cuxhaven
info@voco.de
+49 (0) 4721-719-0 Mo - Fr / 08:00h - 16:00h

Australian sponsor address:
VOCO Australia Pty Ltd
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:*** *Not applicable.*
· ***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
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative

Data sheet for medical devices / EU

Printing date 23.09.2024 Version number 2 (replaces version 1) Revision: 23.09.2024

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

· **1.1 Product identifier**

· **Trade name: Futurabond U bottle**
· **Chemical Identification:**
This product is a medical device in accordance with Directive 93/42/EEC on medical devices or Regulation (EU) 2017/745 (MDR), which is used invasively or in contact with the body. It is therefore exempt from the classification and labelling requirements of Regulations (EC) 1907/2006 (REACH, Art. 2 (6) c)) and (EC) 1272/2008 ((UK) CLP, Article 1 (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.
The product should only be applied by a professionally trained dental practitioner.
· **Application of the substance / the mixture**
Dental adhesive for use with methacrylate-based restorative, core build-up or luting materials.

· **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 in accordance with Directive 93/42/EEC on medical devices or Regulation (EU) 2017/745 (MDR), which is used invasively or in contact with the body. It is therefore exempt from the classification and labelling requirements of Regulations (EC) 1907/2006 (REACH, Art. 2 (6) c)) and (EC) 1272/2008 ((UK) CLP, Article 1 (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.
Aquatic Chronic 3	H412 Harmful to aquatic life with long lasting effects.

· **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:**		
HEMA	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	10-25%
ethanol	Flam. Liq. 2, H225; Eye Irrit. 2, H319	10-25%
HEDMA	Aquatic Chronic 3, H412	10-25%
UDMA	Aquatic Chronic 2, H411; Skin Sens. 1, H317	2.5-10%
Acidic adhesive monomer	Skin Corr. 1A, H314; Eye Irrit. 2, H319	2.5-10%

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Data sheet for medical devices / EU

Trade name: Futurabond U bottle

(Contd. of page 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.

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:***
Rinse with warm water.
If skin irritation continues, consult a doctor.
· ***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.
Rinse out mouth and then drink plenty of water.
· ***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:***
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.*

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Data sheet for medical devices / EU

Trade name: Futurabond U bottle

(Contd. of page 2)

· **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:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored 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.
Avoid contact with the eyes and skin.
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**	Liquid
· **Colour:**	Colourless
· **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:**	Fully miscible.
· **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:**	Liquid
· **Important information on protection of health and environment, and on safety.**	
· **Auto-ignition temperature:**	Product is not selfigniting.

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Data sheet for medical devices / EU

Trade name: Futurabond U bottle

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· **Explosive properties:**	Product does not present an explosion hazard.
· **Change in condition**	The material will cure if exposed to light. Follow the instructions for light curing in the Instructions for Use. The product is cured in combination with Futurabond U bottle DCA.

SECTION 10: Stability and reactivity

· **10.1 Reactivity**
The material will cure if exposed to light.
The product is cured in combination with Futurabond U bottle DCA.
· **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:**
Phenolic substances, especially preparations containing eugenol and thymol, lead to curing disorders.The use of zinc oxide-eugenol cements or other eugenol-containing materials in combination with this product should be avoided.
· **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. For further information, see the instructions for use.

· **Uncleaned packaging:**
· **Recommendation:** Disposal must be made according to official regulations.
· **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

SECTION 14: Transport information

· **14.1 UN number or ID number**	
· **ADR, IMDG, IATA**	UN1170
· **14.2 UN proper shipping name**	
· **ADR**	Void
· **IMDG**	ETHANOL (ETHYL ALCOHOL)

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Data sheet for medical devices / EU

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Trade name: Futurabond U bottle

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· **IATA**	ETHANOL
· **14.3 Transport hazard class(es)**	
· **ADR, IMDG, IATA**	
	
· **Class**	3 Flammable liquids.
· **Label**	3
· **14.4 Packing group**	
· **ADR, IMDG, IATA**	III
· **14.5 Environmental hazards:**	Not applicable.
· **14.6 Special precautions for user**	Warning: Flammable liquids.
· **Hazard identification number (Kemler code):**	30
· **EMS Number:**	F-E,S-D
· **Stowage Category**	A
· **14.7 Maritime transport in bulk according to IMO instruments**	Not applicable.
· **Transport/Additional information:**	
· **ADR**	
· **Limited quantities (LQ)**	5L
· **Excepted quantities (EQ)**	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· **Transport category**	3
· **Tunnel restriction code**	D/E
· **IMDG**	
· **Limited quantities (LQ)**	5L
· **Excepted quantities (EQ)**	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· **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.
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 physical contact are exempt from the requirements for classification and labelling according to Regulations (EC) 1907/2006 (REACH, Art. 2 (6) c)) and (EC) 1272/2008 ((UK) CLP, Article 1 (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

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Data sheet for medical devices / EU

Trade name: Futurabond U bottle

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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**
H225 Highly flammable liquid and vapour.
H314 Causes severe skin burns and eye damage.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H411 Toxic to aquatic life with long lasting effects.
H412 Harmful to aquatic life with long lasting effects.

· **Department issuing Datasheet:** Knowledge Communication Department
· **Contact:**
Global headquarter:
VOCO GmbH
Anton-Flettner-Str. 1-3
D-27472 Cuxhaven
info@voco.de
+49 (0) 4721-719-0 Mo - Fr / 08:00h - 16:00h

Australian sponsor address:
VOCO Australia Pty Ltd
Level 19, 133-145 Castlereagh Street
Sydney, NSW 2000
Email: info@voco.com

For further contact information, please visit www.voco.dental
· **Date of previous version:** 18.07.2024
· **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
Flam. Liq. 2: Flammable liquids – Category 2
Skin Corr. 1A: Skin corrosion/irritation – Category 1A
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
Skin Sens. 1: Skin sensitisation – Category 1
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 09.01.2023 *Version number 16* *Revision: 09.01.2023*

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

· **1.1 Product identifier**

· **Trade name: Ceramic Bond**
· **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** Bonding

· **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**
Flam. Liq. 2 H225 Highly flammable liquid and vapour.
Eye Irrit. 2 H319 Causes serious eye irritation.
STOT SE 3 H336 May cause drowsiness or dizziness.
· **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** GHS02, GHS07
· **Signal word** Danger
· **Hazard statements**
Highly flammable liquid and vapour.
Causes serious eye irritation.
May cause drowsiness or dizziness.
· **Precautionary statements**
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
Use explosion-proof [electrical/ventilating/lighting] equipment.
IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Store locked up.
Dispose of contents/container in accordance with local/regional/national/international regulations.
· **2.3 Other hazards** Use only for intended scope of application
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

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

· **Dangerous components:**

CAS: 67-64-1 EINECS: 200-662-2	acetone	Flam. Liq. 2, H225 Eye Irrit. 2, H319; STOT SE 3, H336	50-100%

SECTION 4: First aid measures

· **4.1 Description of first aid measures**
· **After inhalation:** Seek medical treatment in case of complaints.
· **After skin contact:** Generally the product does not irritate the skin.

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Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 09.01.2023 *Version number 16* *Revision: 09.01.2023*

Trade name: Ceramic Bond

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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.*
· ***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.*
· ***For safety reasons unsuitable extinguishing agents:*** *Water with full jet*
· ***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:***
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***
Ensure good ventilation/exhaustion at the workplace.
For dental use only.
Follow the instructions for use.
No special precautions are necessary if used correctly.
· ***Information about fire - and explosion protection:*** *Keep ignition sources away - Do not smoke.*

· ***7.2 Conditions for safe storage, including any incompatibilities***
· ***Storage:***
· ***Requirements to be met by storerooms and receptacles:*** *No special requirements.*
· ***Information about storage in one common storage facility:*** *Not required.*
· ***Further information about storage conditions:***
Keep container tightly sealed.
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.*

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Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 09.01.2023 Version number 16 Revision: 09.01.2023

Trade name: Ceramic Bond

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· **8.2 Exposure controls**
· **Personal protective equipment:**
· **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
· **Protection of hands:** Not required.
· **Material of gloves** Not applicable.
· **Penetration time of glove material** Not applicable.
· **Eye protection:** Safety glasses

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Fluid
Colour:	Colourless
· **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:**	-19 °C
· **Flammability (solid, gas):**	Not applicable.
· **Decomposition temperature:**	Not determined.
· **Auto-ignition temperature:**	Product is not selfigniting.
· **Explosive properties:**	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
· **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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· **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:**		
CAS: 67-64-1 acetone		
Oral	LD50	5,800 mg/kg (rat)
Dermal	LD50	20,000 mg/kg (rabbit)

· **Primary irritant effect:**
· **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
· **Serious eye damage/irritation**
Causes serious eye irritation.
· **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
· **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**
May cause drowsiness or dizziness.
· **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:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
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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SECTION 14: Transport information

· **14.1 UN-Number**	
· **ADR, IMDG, IATA**	UN1090
· **14.2 UN proper shipping name**	-
· **ADR**	1090 ACETONE
· **IMDG, IATA**	ACETONE
· **14.3 Transport hazard class(es)**	-
· **ADR, IMDG, IATA**	

· **Class**	3 Flammable liquids.
· **Label**	3
· **14.4 Packing group**	-
· **ADR, IMDG, IATA**	II
· **14.5 Environmental hazards:**	Not applicable.
· **Marine pollutant:**	No
· **14.6 Special precautions for user**	Not applicable. Warning: Flammable liquids.
· **Hazard identification number (Kemler code):**	33
· **EMS Number:**	F-E,S-E
· **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**	Not applicable.
· **Transport/Additional information:**	
· **ADR**	
· **Limited quantities (LQ)**	1L
· **Transport category**	2
· **Tunnel restriction code**	D/E
· **UN "Model Regulation":**	UN 1090 ACETONE, 3, II

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.
· **Seveso category** P5c FLAMMABLE LIQUIDS
· **Qualifying quantity (tonnes) for the application of lower-tier requirements** 5,000 t
· **Qualifying quantity (tonnes) for the application of upper-tier requirements** 50,000 t

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:**
Flam. Liq. 2: Flammable liquids – Category 2
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3