Printing date 10.01.2023 Version number 10 Revision: 10.01.2023

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

- · 1.1 Product identifier
- · Trade name: Rebilda DC base
- · 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 Core-build up material
- · Uses advised against No further relevant information available.
- · 1.3 Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

VOCO GmbH

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

- · Further information obtainable from: Scientific department tel. +49 (0)4721-719-0
- · 1.4 Emergency telephone number: Poison Control Center Mainz +49 (0)6131-19240

SECTION 2: Hazards identification

- · 2.2 Label elements
- · Classification according to Regulation (EC) No 1272/2008

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

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

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

As a medical device the product is not subject to labelling regulations under 1272/2008/EC.

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

May cause an allergic skin reaction.

Harmful to aquatic life with long lasting effects.

· Precautionary statements

Avoid breathing dust/fume/gas/mist/vapours/spray.

Avoid release to the environment.

Wear protective gloves.

If skin irritation or rash occurs: Get medical advice/attention.

Specific treatment (see on this label).

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 compone	onents:	
CAS: 72869-86-4	Urethanedimethacrylate	10-25%
EINECS: 276-957-5	Aquatic Chronic 2, H411 Skin Sens. 1B, H317	
	DDDMA	5-10%
	Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	
CAS: 1565-94-2	BIS GMA	2.5-5%
	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	

GB

Printing date 10.01.2023 Version number 10 Revision: 10.01.2023

Trade name: Rebilda DC base

(Contd. of page 1)

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- · After inhalation: Seek medical treatment in case of complaints.
- · After skin contact: Immediately wash with water and soap and rinse thoroughly.
- · After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.
- · After swallowing: If symptoms persist consult doctor.
- · 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- · 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

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

SECTION 6: Accidental release measures

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

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

For dental use only.

No special precautions are necessary if used correctly.

Follow the instructions for use.

- · Information about fire and explosion protection: No special measures required.
- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage:
- Requirements to be met by storerooms and receptacles: No special requirements.
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions: See storage instructions on package
- · 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

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

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

- · Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Personal protective equipment:
- General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

· Respiratory protection: Not required.

(Contd. on page 3)

(Contd. of page 2)

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

Printing date 10.01.2023 Version number 10 Revision: 10.01.2023

Trade name: Rebilda DC base

· Protection of hands:



· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

- · Penetration time of glove material 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: Pasty

Colour: According to product specification

· Odour: Characteristic

· pH-value: Not determined.

· Change in condition

Melting point/freezing point:

Initial boiling point and boiling range: Undetermined.

Flash point: Not applicable.

Auto-ignition temperature: Product is not selfigniting.

Explosive properties: Product does not present an explosion hazard.

Density: Not determined.

Solubility in / Miscibility with water: Not miscible or difficult to mix.

Undetermined.

· Viscosity:

Dynamic: Not determined. **Kinematic:** Not determined.

• 9.2 Other information No further relevant information available.

SECTION 10: Stability and reactivity

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

SECTION 11: Toxicological information

- · 11.1 Information on toxicological effects
- · Acute toxicity Based on available data, the classification criteria are not met.

(Contd. on page 4)

Printing date 10.01.2023 Version number 10 Revision: 10.01.2023

Trade name: Rebilda DC base

(Contd. of page 3)

- · Primary irritant effect:
- · Skin corrosion/irritation

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

- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- · Respiratory or skin sensitisation

May cause an allergic skin reaction.

- · Additional toxicological information:
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- · Reproductive toxicity Based on available data, the classification criteria are not met.
- · STOT-single exposure Based on available data, the classification criteria are not met.
- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and degradability No further relevant information available.
- · 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- Additional ecological information:
- · General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water Do not allow product to reach ground water, water course or sewage system.

- · 12.5 Results of PBT and vPvB assessment
- · **PBT**: Not applicable.
- · vPvB: Not applicable.
- 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

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

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

· 14.1 UN-Number		
· ADR, ADN, IMDG, IATA	Void	
· 14.2 UN proper shipping name		
· ADR, ADN, IMDG, IATA	Void	
· 14.3 Transport hazard class(es)		
· ADR, ADN, IMDG, IATA		
·Class	Void	
· 14.4 Packing group		
· ADR, IMDG, IATA	Void	

(Contd. on page 5)

Printing date 10.01.2023 Version number 10 Revision: 10.01.2023

Trade name: Rebilda DC base

		(Contd. of page 4)
· 14.5 Environmental hazards: · Marine pollutant:	No	
· 14.6 Special precautions for user	Not applicable.	
· 14.7 Transport in bulk according to Ann Marpol and the IBC Code	ex II of Not applicable.	
· UN ''Model Regulation'':	Void	

SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.

SECTION 16: Other information

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

- · Department issuing SDS: Scientific department
- · Contact: Tel.: +49 (0)4721-719-0
- · Abbreviations and acronyms:

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

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

Skin Sens. 1: Skin sensitisation – Category 1

Skin Sens. 1B: Skin sensitisation – Category 1B

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

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

GB

Printing date 10.01.2023 Version number 10 Revision: 10.01.2023

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

- · 1.1 Product identifier
- · Trade name: Rebilda DC catalyst
- · 1.2 Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

- · Application of the substance / the mixture Core-build up material
- · Uses advised against No further relevant information available.
- · 1.3 Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

VOCO GmbH

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

- · Further information obtainable from: Scientific department tel. +49 (0)4721-719-0
- · 1.4 Emergency telephone number: Poison Control Center Mainz +49 (0)6131-19240

SECTION 2: Hazards identification

- · 2.2 Label elements
- · Classification according to Regulation (EC) No 1272/2008

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

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

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

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

As a medical device the product is not subject to labelling regulations under 1272/2008/EC.

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

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

Harmful to aquatic life with long lasting effects.

· Precautionary statements

Avoid breathing dust/fume/gas/mist/vapours/spray.

Avoid release to the environment.

Wear protective gloves / eye protection / face protection.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If skin irritation or rash occurs: Get medical advice/attention.

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 compone	ents:	
Ī		Urethanedimethacrylate	10-25%
	EINECS: 276-957-5	Aquatic Chronic 2, H411 Skin Sens. 1B, H317	

(Contd. on page 2)

Printing date 10.01.2023 Version number 10 Revision: 10.01.2023

Trade name: Rebilda DC catalyst

	(Cor	ntd. of page 1)
	DDDMA	5-10%
	Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	
CAS: 1565-94-2	BIS GMA	2.5-5%
	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	
	benzoyl peroxyde	<i>≤</i> 2.5%
	Org. Perox. B, H241 Eye Irrit. 2, H319; Skin Sens. 1, H317	

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- · After inhalation: Seek medical treatment in case of complaints.
- · After skin contact: Immediately wash with water and soap and rinse thoroughly.
- · After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.
- · After swallowing: If symptoms persist consult doctor.
- · 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- 4.3 Indication of any immediate medical attention and special treatment needed No further relevant information available.

SECTION 5: Firefighting measures

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

SECTION 6: Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures Not required.
- 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- 6.3 Methods and material for containment and cleaning up: Pick up mechanically.
- · 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

For dental use only.

No special precautions are necessary if used correctly.

Follow the instructions for use.

- · Information about fire and explosion protection: No special measures required.
- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage:
- Requirements to be met by storerooms and receptacles: No special requirements.
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions: See storage instructions on package
- · 7.3 Specific end use(s) No further relevant information available.

CE

Printing date 10.01.2023 Version number 10 Revision: 10.01.2023

Trade name: Rebilda DC catalyst

(Contd. of page 2)

SECTION 8: Exposure controls/personal protection

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

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

- · Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

- · Respiratory protection: Not required.
- · Protection of hands:



Protective gloves

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

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

· Eye protection: Safety glasses

SECTION 9: Physical and chemical properties

	I Information on basic physical and chemical properties	
· General Information · Appearance:		
Form:	Pasty	
Colour:	Whitish	
· Odour:	Characteristic	
· pH-value:	Not determined.	
· Change in condition Melting point/freezing point: Initial boiling point and boiling range:	Undetermined. Undetermined.	
· Flash point:	Not applicable.	
Auto-ignition temperature:	Product is not selfigniting.	
· Explosive properties:	Product does not present an explosion hazard.	
Density:	Not determined.	
· Solubility in / Miscibility with water:	Not miscible or difficult to mix.	
· Viscosity: Dynamic: Kinematic:	Not determined. Not determined.	

(Contd. on page 4)

Printing date 10.01.2023 Version number 10 Revision: 10.01.2023

Trade name: Rebilda DC catalyst

(Contd. of page 3)

9.2 Other information

No further relevant information available.

SECTION 10: Stability and reactivity

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

SECTION 11: Toxicological information

- · 11.1 Information on toxicological effects
- · Acute toxicity Based on available data, the classification criteria are not met.
- · Primary irritant effect:
- · Skin corrosion/irritation

Testing according to ISO 10993-1/10993-10 showed no skin irritation for this product when fully cured Not cured:

Causes skin irritation.

· Serious eye damage/irritation

Causes serious eye irritation.

· Respiratory or skin sensitisation

May cause an allergic skin reaction.

- · 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.
- $\cdot \textbf{STOT-single exposure} \ \textit{Based on available data, the classification criteria are not met.}$
- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and degradability No further relevant information available.
- · 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water Do not allow product to reach ground water, water course or sewage system.

- · 12.5 Results of PBT and vPvB assessment
- · **PBT**: Not applicable.
- · vPvB: Not applicable.
- · 12.6 Other adverse effects No further relevant information available.

CD.

Printing date 10.01.2023 Version number 10 Revision: 10.01.2023

Trade name: Rebilda DC catalyst

(Contd. of page 4)

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- Recommendation

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

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

SECTION 14: Transport information	tion	
14.1 UN-Number		
ADR, ADN, IMDG, IATA	Void	
14.2 UN proper shipping name		
ADR, ADN, IMDG, IATA	Void	
14.3 Transport hazard class(es)		
ADR, ADN, IMDG, IATA		
Class	Void	
14.4 Packing group		
ADR, IMDG, IATA	Void	
14.5 Environmental hazards:		
Marine pollutant:	No	
14.6 Special precautions for user	Not applicable.	
· 14.7 Transport in bulk according to Annex II of		
Marpol and the IBC Code	Not applicable.	
UN ''Model Regulation'':	Void	

SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.

SECTION 16: Other information

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

- · Department issuing SDS: Scientific department
- · Contact: Tel.: +49 (0)4721-719-0
- · Abbreviations and acronyms:

Org. Perox. B: Organic peroxides – Type B

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

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

Skin Sens. 1: Skin sensitisation – Category 1

Skin Sens. 1B: Skin sensitisation – Category 1B

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

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