

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

1.1 Product identifier

• **Trade name:** Quick Up Adhäsiv

• **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 silanisation agent

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:

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

Eye Irrit. 2 H319 Causes serious eye irritation.

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

STOT SE 3 H336 May cause drowsiness or dizziness.

• **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:**

acetone	Flam. Liq. 2, H225; Eye Irrit. 2, H319; STOT SE 3, H336, EUH066	75-100%
HEMA	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	2.5-10%

• **Additional information:**

Further information on ingredients can be found in the instructions for use.

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Trade name: Quick Up Adhüsiv

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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:**
Rinse out mouth and then drink plenty of water.
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.

EU

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Trade name: Quick Up Adhüsiv

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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**

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.

· **Explosive properties:**

Product does not present an explosion hazard.

SECTION 10: Stability and reactivity· **10.1 Reactivity** No further relevant information available.

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Trade name: Quick Up Adhüsiv

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- **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. For further information, see the instructions for use.

· Uncleaned packaging:

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

SECTION 14: Transport information

· 14.1 UN number or ID 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.

· 14.6 Special precautions for user

Warning: Flammable liquids.

· **Hazard identification number (Kemler code):** 30

· **EMS Number:** F-E,S-D

· **Stowage Category** E

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Trade name: Quick Up Adhüsiv

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· 14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
· Transport/Additional information:	
· ADR	
· Limited quantities (LQ)	1L
· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· Transport category	2
· Tunnel restriction code	D/E
· IMDG	
· Limited quantities (LQ)	1L
· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· 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**
Regulation (EU) 2017/745
Medical Devices Regulation

Directive 93/42/EEC concerning medical devices

This product is regulated by Regulation (EU) No 2019/1148 - Regulation on the marketing and use of explosives precursors: All suspicious transactions and the loss and theft of significant quantities must be reported to the relevant national contact point. See https://ec.europa.eu/home-affairs/sites/homeaffairs/files/what-we-do/policies/crisis-and-terrorism/explosives/explosives-precursors/docs/list_of_competent_authorities_and_national_contact_points_en.pdf. Translated with DeepL.com (free version)

- **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 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.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness.
EUH066 Repeated exposure may cause skin dryness or cracking.

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Trade name: Quick Up Adhüsiv

(Contd. of page 5)

· **Department issuing Datasheet:** Knowledge Communication Department

· **Contact:**

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· **Date of previous version:** 24.09.2024

· **Version number of previous version:** 2

· **Abbreviations and acronyms:**

Flam. Liq. 2: Flammable liquids – Category 2

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

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

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

1.1 Product identifier

· **Trade name:** Quick Up base

· **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**

Attachment - fastening material and repair material for secondary elements

1.3 Details of the supplier of the data sheet

· **Manufacturer/Supplier:**

VOCO GmbH

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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 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:

Eye Irrit. 2 H319 Causes serious eye irritation.

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	25-50%
Catalyst	Eye Dam. 1, H318; Acute Tox. 4, H302; Skin Sens. 1, H317; Aquatic Chronic 3, H412	1-2.5%

· **Additional information:**

Further information on ingredients can be found in the instructions for use.

(Contd. on page 2)

Trade name: Quick Up base

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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:**
Rinse out mouth and then drink plenty of water.
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.

EU

(Contd. on page 3)

Trade name: Quick Up base

(Contd. of page 2)

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**

pasty

· **Colour:**

Red

· **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.

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Trade name: Quick Up base

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· **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:**

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:** *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

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Trade name: Quick Up base

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· 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 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 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**
H302 Harmful if swallowed.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
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:**
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For further contact information, please visit www.voco.dental

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Revision: 13.08.2024

Trade name: Quick Up base

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· **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

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

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

EU

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

1.1 Product identifier

· **Trade name:** Quick Up catalyst

· **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**

Attachment - fastening material and repair material for secondary elements

1.3 Details of the supplier of the data sheet

· **Manufacturer/Supplier:**

VOCO GmbH

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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 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 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	25-50%
Aquatic Chronic 2, H411; Skin Sens. 1, H317	
benzoyl peroxide	1-2.5%
Org. Perox. C, H242; Aquatic Chronic 1, H410; Eye Irrit. 2, H319; Skin Sens. 1, H317	

· **Additional information:**

Further information on ingredients can be found in the instructions for use.

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Trade name: Quick Up catalyst

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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:**
Rinse out mouth and then drink plenty of water.
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.

EU

(Contd. on page 3)

Trade name: Quick Up catalyst

(Contd. of page 2)

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**

pasty

· **Colour:**

Whitish

· **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.

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Trade name: Quick Up catalyst

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· **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:**

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:** 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

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· 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 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 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**
H242 Heating may cause a fire.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H410 Very toxic to aquatic life with long lasting effects.
H411 Toxic to aquatic life with long lasting effects.
- **Department issuing Datasheet:** Knowledge Communication Department
- **Contact:**
Global headquarter:
VOCO GmbH
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D-27472 Cuxhaven
info@voco.de
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Australian sponsor address:
VOCO Australia Pty Ltd
Level 19, 133-145 Castlereagh Street
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Trade name: Quick Up catalyst

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· **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

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

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

EU

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

1.1 Product identifier

· **Trade name:** Quick Up LC

· **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** Luting and repair material for attachments.

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 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	25-50%
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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.

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Trade name: Quick Up LC

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- **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:**
Rinse out mouth and then drink plenty of water.
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:**
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.

(Contd. on page 3)

Trade name: **Quick Up LC**

(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.
 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: | Red |
| · 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 | 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** 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.

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Trade name: Quick Up LC

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· 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:** 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

(Contd. on page 5)

Trade name: Quick Up LC

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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 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

H317 May cause an allergic skin reaction.

H411 Toxic to aquatic life with long lasting effects.

Department issuing Datasheet: Knowledge Communication Department

Contact:

Global headquarter:

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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: 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

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 Sens. 1: Skin sensitisation – Category 1

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

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

1.1 Product identifier

· **Trade name:** Fit Test C&B 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.

The product should only be applied by a professionally trained dental practitioner.

· **Application of the substance / the mixture** Dental impression material

1.3 Details of the supplier of the data sheet

· **Manufacturer/Supplier:**

VOCO GmbH

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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:

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:** Mixture of non-hazardous substances.

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:**

Rinse out mouth and then drink plenty of water.

(Contd. on page 2)

Trade name: *Fit Test C&B base*

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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:**
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.

EU

(Contd. on page 3)

Trade name: Fit Test C&B base

(Contd. of page 2)

SECTION 9: Physical and chemical properties**· 9.1 Information on basic physical and chemical properties****· General Information**

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

· 9.2 Other information

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

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:

The following materials can prevent or delay the setting reaction of Fit Test C & B: condensation-curing silicone, polysulphide impression materials, materials containing eugenol, incompletely cured acrylics and latex gloves. These materials must not be used when working with Fit Test C & B.

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

EU

(Contd. on page 4)

Trade name: *Fit Test C&B base*

(Contd. of page 3)

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:** 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)

Trade name: Fit Test C&B 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.

· **Department issuing Datasheet:** Knowledge Communication Department

· **Contact:**

Global headquarter:

VOCO GmbH

Anton-Flettner-Str. 1-3

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Australien 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

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

1.1 Product identifier

· **Trade name:** Fit Test C&B 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.

The product should only be applied by a professionally trained dental practitioner.

· **Application of the substance / the mixture** Dental impression material

1.3 Details of the supplier of the data sheet

· **Manufacturer/Supplier:**

VOCO GmbH

Anton-Flettner-Str. 1-3

D-27472 Cuxhaven

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+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:** Mixture of non-hazardous substances.

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:**

Rinse out mouth and then drink plenty of water.

(Contd. on page 2)

Trade name: Fit Test C&B catalyst

(Contd. of page 1)

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:**
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.

EU

(Contd. on page 3)

Trade name: Fit Test C&B catalyst

(Contd. of page 2)

SECTION 9: Physical and chemical properties**· 9.1 Information on basic physical and chemical properties****· General Information**

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

· 9.2 Other information

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

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:

The following materials can prevent or delay the setting reaction of Fit Test C & B: condensation-curing silicone, polysulphide impression materials, materials containing eugenol, incompletely cured acrylics and latex gloves. These materials must not be used when working with Fit Test C & B.

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

EU

(Contd. on page 4)

Trade name: *Fit Test C&B catalyst*

(Contd. of page 3)

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:** 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)

Trade name: Fit Test C&B catalyst

(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.

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