

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

Printing date 14.12.2016

Version number 6

Revision: 14.12.2016

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

- **1.1 Product identifier**
- **Trade name: Fit Test C&B 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** Dental impression material
- **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

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
The product is not classified according to the CLP regulation.
- **2.2 Label elements**
- **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** Void
- **Hazard statements** Void
- **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 non-hazardous substances.
- **Dangerous components:** Void

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:** Seek medical treatment in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **4.3 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.

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Trade name: Fit Test C&B Base

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- 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.
- **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

- **Additional information about design of technical facilities:** No further data; see item 7.
- 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:** 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:** Not required.
- **Material of gloves:** Not applicable.

SECTION 9: Physical and chemical properties

- 9.1 Information on basic physical and chemical properties
- **General Information**
- **Appearance:**
- **Form:** Viscous
- **Colour:** Colourless
- **Odour:** Characteristic
- **pH-value:** Not determined.
- **Change in condition**
- **Melting point/Melting range:** Undetermined.
- **Boiling point/Boiling range:** Undetermined.
- **Flash point:** 131 °C

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Trade name: Fit Test C&B Base

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- | | |
|--|---|
| · Self-igniting: | Product is not selfigniting. |
| · Danger of explosion: | Product does not present an explosion hazard. |
| · Density: | Not determined. |
| · Solubility in / Miscibility with water: | Not miscible or difficult to mix. |
| · Viscosity: | |
| Dynamic: | Not determined. |
| Kinematic: | Not determined. |
| · 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** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **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 undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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Trade name: Fit Test C&B Base

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- **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.

SECTION 14: Transport information

- | | |
|---|-----------------|
| · 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:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
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
- *** Data compared to the previous version altered.**

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

- **1.1 Product identifier**
- **Trade name:** *Fit Test C&B 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** *Dental impression material*
- **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

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
The product is not classified according to the CLP regulation.
- **2.2 Label elements**
- **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** *Void*
- **Hazard statements** *Void*
- **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 non-hazardous substances.*
- **Dangerous components:** *Void*

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** *No special measures required.*
- **After inhalation:** *Seek medical treatment in case of complaints.*
- **After skin contact:** *Generally the product does not irritate the skin.*
- **After eye contact:** *Rinse opened eye for several minutes under running water.*
- **After swallowing:** *If symptoms persist consult doctor.*
- **4.2 Most important symptoms and effects, both acute and delayed** *No further relevant information available.*
- **4.3 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.*

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Trade name: *Fit Test C&B Catalyst*

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- **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.*
- **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

- **Additional information about design of technical facilities:** *No further data; see item 7.*
- **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:** *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:** *Not required.*
- **Material of gloves** *Not applicable.*

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**
- **Form:** *Viscous*
- **Colour:** *Light blue*
- **Odour:** *Characteristic*
- **pH-value:** *Not determined.*
- **Change in condition**
- **Melting point/Melting range:** *Undetermined.*
- **Boiling point/Boiling range:** *Undetermined.*
- **Flash point:** *131 °C*

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Trade name: Fit Test C&B Catalyst

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|--|---|
| · Self-igniting: | Product is not selfigniting. |
| · Danger of explosion: | Product does not present an explosion hazard. |
| · Density: | Not determined. |
| · Solubility in / Miscibility with water: | Not miscible or difficult to mix. |
| · Viscosity: | |
| Dynamic: | Not determined. |
| Kinematic: | Not determined. |
| · 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.

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- **11.1 Information on toxicological effects**
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- **Primary irritant effect:**
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- **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 undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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Trade name: Fit Test C&B Catalyst

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- **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.

SECTION 14: Transport information

- | | |
|---|-----------------|
| · 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.

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- *** Data compared to the previous version altered.**