

**Data sheet for medical devices / EU**

Printing date 23.08.2024

Version number 1

Revision: 13.08.2024

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier****Trade name:** Admira Fusion x-tra**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 filling material**1.3 Details of the supplier of the data sheet****Manufacturer/Supplier:**

VOCO GmbH

Anton-Flettner-Str. 1-3

D-27472 Cuxhaven

info@voco.de

+49 (0) 4721-719-0 Mo - Fr / 08:00h - 16:00h

**SECTION 2: Hazards identification****2.1 Classification of the substance or mixture****Classification according to Regulation (EC) No 1272/2008**

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

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

**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:**

|         |                                         |        |
|---------|-----------------------------------------|--------|
| ORMOCER | Skin Irrit. 2, H315; Eye Irrit. 2, H319 | 10-25% |
|---------|-----------------------------------------|--------|

**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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- **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.

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- **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**

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

· **9.2 Other information**

- |                                                                                        |                                                                                                                      |
|----------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|
| · <b>Appearance:</b>                                                                   |                                                                                                                      |
| · <b>Form:</b>                                                                         | Pasty                                                                                                                |
| · <b>Important information on protection of health and environment, and on safety.</b> |                                                                                                                      |
| · <b>Auto-ignition temperature:</b>                                                    | Not determined.                                                                                                      |
| · <b>Explosive properties:</b>                                                         | Product does not present an explosion hazard.                                                                        |
| · <b>Change in condition</b>                                                           | The material will cure if exposed to light.<br>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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**· 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

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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***H315 Causes skin irritation.**H319 Causes serious eye irritation.***Department issuing Datasheet:** Knowledge Communication Department**Contact:***Global headquarter:**VOCO GmbH**Anton-Flettner-Str. 1-3**D-27472 Cuxhaven**info@voco.de**+49 (0) 4721-719-0 Mo - Fr / 08:00h - 16:00h**Australian sponsor address:**VOCO Australia Pty Ltd**Level 19, 133-145 Castlereagh Street**Sydney, NSW 2000**Email: info@voco.com**For further contact information, please visit [www.voco.dental](http://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 Irrit. 2: Skin corrosion/irritation – Category 2**Eye Irrit. 2: Serious eye damage/eye irritation – Category 2*

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Printing date 03.09.2024

Version number 1

Revision: 25.07.2024

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier****Trade name:** Futurabond U Liquid 1**Chemical Identification:**

This product is a medical device in accordance with Directive 93/42/EEC on medical devices or Regulation (EU) 2017/745 (MDR), which is used invasively or in contact with the body. It is therefore exempt from the classification and labelling requirements of Regulations (EC) 1907/2006 (REACH, Art. 2 (6) c)) and (EC) 1272/2008 ((UK) CLP, Article 1 (5) d).

A safety data sheet is not required by law for this product. This information is provided on a voluntary basis in the form of this Medical Devices Data Sheet.

**Product category** Dental medical device**Article category**

The information relevant for the application and for the safety of users and patients is defined in the product-specific directions for use. The instructions for use must be observed.

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

**Application of the substance / the mixture** dental adhesive**1.3 Details of the supplier of the data sheet****Manufacturer/Supplier:**

VOCO GmbH

Anton-Flettner-Str. 1-3

D-27472 Cuxhaven

info@voco.de

+49 (0) 4721-719-0 Mo - Fr / 08:00h - 16:00h

**SECTION 2: Hazards identification****2.1 Classification of the substance or mixture****Classification according to Regulation (EC) No 1272/2008**

This product is a medical device in accordance with Directive 93/42/EEC on medical devices or Regulation (EU) 2017/745 (MDR), which is used invasively or in contact with the body. It is therefore exempt from the classification and labelling requirements of Regulations (EC) 1907/2006 (REACH, Art. 2 (6) c)) and (EC) 1272/2008 ((UK) CLP, Article 1 (5) d).

The classification criteria of Regulation (EC) No 1272/2008 are not directly applicable to this product, but are considered by us as an orienting basis for assessment. The health and environmental hazards have been assessed and classified on the basis of the information known to us on the components and their reaction processes. The following hazards based on the classification criteria of Regulation (EC) No 1272/2008 for humans and the environment cannot be excluded:

Skin Corr. 1A H314 Causes severe skin burns and eye damage.

Eye Dam. 1 H318 Causes serious eye damage.

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

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

**2.3 Other hazards****Results of PBT and vPvB assessment****PBT:** Not applicable.**vPvB:** Not applicable.**SECTION 3: Composition/information on ingredients****3.2 Mixtures****Description:** Mixture of substances listed below with nonhazardous additions.**Dangerous components:**

|                         |                                                             |         |
|-------------------------|-------------------------------------------------------------|---------|
| HEMA                    | Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317 | 25-50%  |
| Acidic adhesive monomer | Skin Corr. 1A, H314; Eye Irrit. 2, H319                     | 2.5-10% |
| UDMA                    | Aquatic Chronic 2, H411; Skin Sens. 1, H317                 | 2.5-10% |
| BHT                     | Aquatic Chronic 1, H410                                     | 0.1-1%  |

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**· Additional information:***Further information on ingredients can be found in the instructions for use.**In case of known hypersensitivity to the ingredients mentioned in the instructions for use, do not use the product.***SECTION 4: First aid measures****· 4.1 Description of first aid measures****· General information:** *No special measures required.***· After inhalation:** *Supply fresh air; consult doctor in case of complaints.***· After skin contact:***Rinse with warm water.**If skin irritation continues, consult a doctor.***· After eye contact:***Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.***· After swallowing:***If symptoms persist consult doctor.**Rinse out mouth and then drink plenty of water.***· 4.2 Most important symptoms and effects, both acute and delayed** *No further relevant information available.***· 4.3 In case of contact with mucous membranes during treatment:***Avoid contact with the oral mucosa. Remove excess immediately.***SECTION 5: Firefighting measures****· 5.1 Extinguishing media****· Suitable extinguishing agents:** *Use fire extinguishing methods suitable to surrounding conditions.***· 5.2 Special hazards arising from the substance or mixture** *No further relevant information available.***· 5.3 Advice for firefighters****· Protective equipment:** *No special measures required.***SECTION 6: Accidental release measures****· 6.1 Personal precautions, protective equipment and emergency procedures** *Not required.***· 6.2 Environmental precautions:** *No special measures required.***· 6.3 Methods and material for containment and cleaning up:** *Pick up mechanically.***· 6.4 Reference to other sections***See Section 7 for information on safe handling.**See Section 8 for information on personal protection equipment.**See Section 13 for disposal information.***SECTION 7: Handling and storage****· 7.1 Precautions for safe handling***No special precautions are necessary if used correctly.**For use in dental application only.**Observe the instructions for use! This contains the relevant application and safety information for the use of this product.***· Information about fire - and explosion protection:** *No special measures required.***· 7.2 Conditions for safe storage, including any incompatibilities****· Storage:****· Requirements to be met by storerooms and receptacles:** *No special requirements.***· Information about storage in one common storage facility:** *Not required.*

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**Trade name: Futurabond U Liquid 1**

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

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

**· 9.2 Other information****· Appearance:****· Form:** *Liquid***· Important information on protection of health and environment, and on safety.****· Auto-ignition temperature:** *Product is not selfigniting.*

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- **Explosive properties:**
- **Change in condition**

Product does not present an explosion hazard.  
The material will cure if exposed to light.  
Follow the instructions for light curing in the Instructions for Use.

**SECTION 10: Stability and reactivity**

- **10.1 Reactivity**

After mixing Liquid 1 and Liquid 2, the product is cured in accordance with 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:** Disposal must be made according to official regulations.

**SECTION 14: Transport information**

- **14.1 UN number or ID number**

- **ADR, IMDG, IATA**

Void

- **14.2 UN proper shipping name**

- **ADR, IMDG, IATA**

Void

- **14.3 Transport hazard class(es)**

- **ADR, ADN, IMDG, IATA**

- **Class**

Void

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|-----------------------------------------------------------------------|-----------------|
| · <b>14.4 Packing group</b><br>· <b>ADR, IMDG, IATA</b>               | Void            |
| · <b>14.5 Environmental hazards:</b>                                  | Not applicable. |
| · <b>14.6 Special precautions for user</b>                            | Not applicable. |
| · <b>14.7 Maritime transport in bulk according to IMO instruments</b> | Not applicable. |
| · <b>UN "Model Regulation":</b>                                       | 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**  
H314 Causes severe skin burns and eye damage.  
H315 Causes skin irritation.  
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:**  
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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

Skin Corr. 1A: Skin corrosion/irritation – Category 1A

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

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

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

Skin Sens. 1: Skin sensitisation – Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

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

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

EU

**SECTION 1: Identification of the substance/mixture and of the company/undertaking**· **1.1 Product identifier**· **Trade name:** Futurabond U Liquid 2· **Chemical Identification:**

*This product is a medical device in accordance with Directive 93/42/EEC on medical devices or Regulation (EU) 2017/745 (MDR), which is used invasively or in contact with the body. It is therefore exempt from the classification and labelling requirements of Regulations (EC) 1907/2006 (REACH, Art. 2 (6) c)) and (EC) 1272/2008 ((UK) CLP, Article 1 (5) d).*

*A safety data sheet is not required by law for this product. This information is provided on a voluntary basis in the form of this Medical Devices Data Sheet.*

· **Product category** Dental medical device· **Article category**

*The information relevant for the application and for the safety of users and patients is defined in the product-specific directions for use. The instructions for use must be observed.*

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

· **Application of the substance / the mixture** dental adhesive· **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:*

*Eye Irrit. 2 H319 Causes serious eye irritation.*

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

· **2.3 Other hazards**· **Results of PBT and vPvB assessment**· **PBT:** Not applicable.· **vPvB:** Not applicable.**SECTION 3: Composition/information on ingredients**· **3.2 Mixtures**· **Description:** Mixture of substances listed below with nonhazardous additions.· **Dangerous components:**

|                                                                                   |         |
|-----------------------------------------------------------------------------------|---------|
| ethanol                                                                           | 50-75%  |
| Flam. Liq. 2, H225; Eye Irrit. 2, H319                                            |         |
| Initiator                                                                         | 2.5-10% |
| Acute Tox. 3, H301                                                                |         |
| Catalyst                                                                          | 1-2.5%  |
| Eye Dam. 1, H318; Acute Tox. 4, H302; Skin Sens. 1, H317; Aquatic Chronic 3, H412 |         |

· **Additional information:**

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

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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:**  
If symptoms persist consult doctor.  
Rinse out mouth and then drink plenty of water.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **4.3 In case of contact with mucous membranes during treatment:**  
Avoid contact with the oral mucosa. Remove excess immediately.

**SECTION 5: Firefighting measures**

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

**SECTION 6: Accidental release measures**

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

**SECTION 7: Handling and storage**

- **7.1 Precautions for safe handling**  
No special precautions are necessary if used correctly.  
For use in dental application only.  
Observe the instructions for use! This contains the relevant application and safety information for the use of this product.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**  
Please observe the storage instructions on the packaging and in the instructions for use.

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Trade name: Futurabond U Liquid 2

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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:**

Partly soluble.

· **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.

· **Change in condition**

Not applicable.

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**Trade name: Futurabond U Liquid 2**

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**SECTION 10: Stability and reactivity****· 10.1 Reactivity**

After mixing Liquid 1 and Liquid 2, the product is cured in accordance with 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:** Disposal must be made according to official regulations.**SECTION 14: Transport information****· 14.1 UN number or ID number****· ADR, IMDG, IATA**

Void

**· 14.2 UN proper shipping name****· ADR, IMDG, IATA**

Void

**· 14.3 Transport hazard class(es)****· ADR, ADN, IMDG, IATA****· Class**

Void

**· 14.4 Packing group****· ADR, IMDG, IATA**

Void

**· 14.5 Environmental hazards:**

Not applicable.

**· 14.6 Special precautions for user**

Not applicable.

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**Trade name: Futurabond U Liquid 2**

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- |                                                                       |                 |
|-----------------------------------------------------------------------|-----------------|
| · <b>14.7 Maritime transport in bulk according to IMO instruments</b> | Not applicable. |
| · <b>UN "Model Regulation":</b>                                       | 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**  
H225 Highly flammable liquid and vapour.  
H301 Toxic if swallowed.  
H302 Harmful if swallowed.  
H317 May cause an allergic skin reaction.  
H318 Causes serious eye damage.  
H319 Causes serious eye irritation.  
H412 Harmful to aquatic life with long lasting effects.
- **Department issuing Datasheet:** Knowledge Communication Department
- **Contact:**  
Global headquarter:  
VOCO GmbH  
Anton-Flettner-Str. 1-3  
D-27472 Cuxhaven  
info@voco.de  
+49 (0) 4721-719-0 Mo - Fr / 08:00h - 16:00h

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

For further contact information, please visit [www.voco.dental](http://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)

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*IMDG: International Maritime Code for Dangerous Goods**IATA: International Air Transport Association**GHS: Globally Harmonised System of Classification and Labelling of Chemicals**EINECS: European Inventory of Existing Commercial Chemical Substances**ELINCS: European List of Notified Chemical Substances**CAS: Chemical Abstracts Service (division of the American Chemical Society)**PBT: Persistent, Bioaccumulative and Toxic**vPvB: very Persistent and very Bioaccumulative**Flam. Liq. 2: Flammable liquids – Category 2**Acute Tox. 3: Acute toxicity – Category 3**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 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3*

EU

# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 09.09.2016

Version number 18

Revision: 09.09.2016

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

- **1.1 Product identifier**
- **Trade name: Futurabond U Liquid 1**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** Bonding
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
VOCO GmbH  
Anton-Flettner-Str. 1-3  
D-27472 Cuxhaven
- **Further information obtainable from:** Scientific department tel. +49 (0)4721-719-0
- **1.4 Emergency telephone number:** Poison Control Center Mainz +49 (0)6131-19240

### SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
Skin Irrit. 2 H315 Causes skin irritation.  
Eye Irrit. 2 H319 Causes serious eye irritation.  
Skin Sens. 1 H317 May cause an allergic skin reaction.  
STOT SE 3 H335 May cause respiratory irritation.
- **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** GHS07
- **Hazard statements**  
Causes skin irritation.  
Causes serious eye irritation.  
May cause an allergic skin reaction.  
May cause respiratory irritation.
- **Precautionary statements**  
Wear protective gloves/protective clothing/eye protection/face protection.  
Call a doctor if you feel unwell.  
If skin irritation occurs: Get medical advice/attention.  
IF ON SKIN: Wash with plenty of soap and water.  
Store locked up.  
Dispose of contents/container in accordance with local/regional/national/international regulations.
- **2.3 Other hazards** Use only for intended scope of application
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### SECTION 3: Composition/information on ingredients

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

· **Dangerous components:**

|                                    |                                                                                                             |        |
|------------------------------------|-------------------------------------------------------------------------------------------------------------|--------|
| CAS: 1565-94-2                     | BIS GMA<br>Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317                                      | 25-50% |
| CAS: 868-77-9<br>EINECS: 212-782-2 | 2-hydroxyethyl methacrylate<br>Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335 | 25-50% |

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**Trade name: Futurabond U Liquid 1**

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|                                      |                                                                                                                      |        |
|--------------------------------------|----------------------------------------------------------------------------------------------------------------------|--------|
| CAS: 6606-59-3<br>EINECS: 229-551-7  | 1,6-hexanediylbismethacrylate<br>Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335                            | 10-25% |
|                                      | Acidic adhesive monomer<br>Skin Corr. 1B, H314<br>Eye Irrit. 2, H319                                                 | 5-10%  |
| CAS: 72869-86-4<br>EINECS: 276-957-5 | Urethanedimethacrylate<br>Aquatic Chronic 3, H412                                                                    | 5-10%  |
|                                      | Catalyst<br>Aquatic Acute 1, H400<br>Acute Tox. 4, H302; Acute Tox. 4, H332; Skin Irrit. 2, H315; Eye Irrit. 2, H319 | ≤ 2.5% |

· **Additional information:** For the wording of the listed hazard phrases refer to section 16.

### SECTION 4: First aid measures

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

### SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **6.4 Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

### SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** 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:** See storage instructions on package
- **Information about storage in one common storage facility:** Not required.

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- **Further information about storage conditions:** Keep container tightly sealed.
- **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:**  
Immediately remove all soiled and contaminated clothing  
Wash hands before breaks and at the end of work.  
Avoid contact with the eyes and skin.
- **Respiratory protection:** Not required.
- **Protection of hands:**



Protective gloves

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

### SECTION 9: Physical and chemical properties

#### · 9.1 Information on basic physical and chemical properties

##### · General Information

##### · Appearance:

|                  |                 |
|------------------|-----------------|
| Form:            | Fluid           |
| Colour:          | Colourless      |
| Odour:           | Characteristic  |
| Odour threshold: | Not determined. |

|                      |     |
|----------------------|-----|
| · pH-value at 20 °C: | 2.3 |
|----------------------|-----|

##### · Change in condition

|                              |               |
|------------------------------|---------------|
| Melting point/Melting range: | Undetermined. |
| Boiling point/Boiling range: | Undetermined. |

|                |                 |
|----------------|-----------------|
| · Flash point: | Not applicable. |
|----------------|-----------------|

|                                  |                 |
|----------------------------------|-----------------|
| · Flammability (solid, gaseous): | Not applicable. |
|----------------------------------|-----------------|

|                              |                 |
|------------------------------|-----------------|
| · Decomposition temperature: | Not determined. |
|------------------------------|-----------------|

|                  |                              |
|------------------|------------------------------|
| · Self-igniting: | Product is not selfigniting. |
|------------------|------------------------------|

|                        |                                               |
|------------------------|-----------------------------------------------|
| · Danger of explosion: | Product does not present an explosion hazard. |
|------------------------|-----------------------------------------------|

|                     |                       |
|---------------------|-----------------------|
| · Density at 20 °C: | 1.1 g/cm <sup>3</sup> |
| · Relative density  | Not determined.       |
| · Vapour density    | Not determined.       |

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**Trade name: Futurabond U Liquid 1**

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- |                                                   |                                            |
|---------------------------------------------------|--------------------------------------------|
| · <b>Evaporation rate</b>                         | Not determined.                            |
| · <b>Solubility in / Miscibility with water:</b>  | Not miscible or difficult to mix.          |
| · <b>Partition coefficient (n-octanol/water):</b> | Not determined.                            |
| · <b>Viscosity:</b>                               |                                            |
| <b>Dynamic:</b>                                   | Not determined.                            |
| <b>Kinematic:</b>                                 | Not determined.                            |
| · <b>9.2 Other information</b>                    | 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.

#### · **LD/LC50 values relevant for classification:**

|                                |
|--------------------------------|
| <b>Acidic adhesive monomer</b> |
|--------------------------------|

|                              |
|------------------------------|
| Oral LD50 > 2000 mg/kg (rat) |
|------------------------------|

- **Primary irritant effect:**
- **Skin corrosion/irritation**  
Testing according to ISO 10993-1/10993-10 showed no skin irritation for this product when fully cured  
Causes skin irritation.
- **Serious eye damage/irritation**  
Causes serious eye irritation.
- **Respiratory or skin sensitisation**  
May cause an allergic skin reaction.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure**  
May cause respiratory irritation.
- **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.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.

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**Trade name: Futurabond U Liquid 1**

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- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

### SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**  
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### SECTION 14: Transport information

- |                                                                                  |                                                                                                                       |
|----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|
| · <b>14.1 UN-Number</b>                                                          | Attention: special provisions A197 IATA, 375 ADR and/or IMDG-Code paragraph 2.10.2.7 may be applied during transport. |
| · <b>14.2 UN proper shipping name</b>                                            | -                                                                                                                     |
| · <b>14.3 Transport hazard class(es)</b>                                         | -                                                                                                                     |
| · <b>14.4 Packing group</b>                                                      | -                                                                                                                     |
| · <b>14.5 Environmental hazards:</b>                                             | Not applicable.                                                                                                       |
| · <b>Marine pollutant:</b>                                                       | No                                                                                                                    |
| · <b>14.6 Special precautions for user</b>                                       | Not applicable.                                                                                                       |
| · <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b> | Not applicable.                                                                                                       |

### 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.
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

### 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:**  
 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)  
 LC50: Lethal concentration, 50 percent  
 LD50: Lethal dose, 50 percent  
 PBT: Persistent, Bioaccumulative and Toxic  
 vPvB: very Persistent and very Bioaccumulative  
 Acute Tox. 4: Acute toxicity – Category 4  
 Skin Corr. 1B: Skin corrosion/irritation – Category 1B  
 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

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*STOT SE 3: Specific target organ toxicity (single exposure) – Category 3**Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1**Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3***· \* Data compared to the previous version altered.**

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# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 09.09.2016

Version number 14

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

- **1.1 Product identifier**
- **Trade name: Futurabond U Liquid 2**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** Bonding
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
VOCO GmbH  
Anton-Flettner-Str. 1-3  
D-27472 Cuxhaven
- **Further information obtainable from:** Scientific department tel. +49 (0)4721-719-0
- **1.4 Emergency telephone number:** Poison Control Center Mainz +49 (0)6131-19240

### SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
Flam. Liq. 3 H226 Flammable liquid and vapour.
- **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** GHS02
- **Hazard statements**  
Flammable liquid and vapour.
- **Precautionary statements**  
Wear protective gloves/protective clothing/eye protection/face protection.  
Keep container tightly closed.  
In case of fire: Use for extinction: CO<sub>2</sub>, sand, extinguishing powder.  
Dispose of contents/container in accordance with local/regional/national/international regulations.
- **2.3 Other hazards** Use only for intended scope of application
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### SECTION 3: Composition/information on ingredients

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

· **Dangerous components:**

|                                   |           |                                        |         |
|-----------------------------------|-----------|----------------------------------------|---------|
| CAS: 64-17-5<br>EINECS: 200-578-6 | ethanol   | Flam. Liq. 2, H225                     | 50-100% |
|                                   | Initiator | Acute Tox. 3, H301                     | 2.5-5%  |
|                                   | Catalyst  | Eye Dam. 1, H318<br>Acute Tox. 4, H302 | 1-2.5%  |

### SECTION 4: First aid measures

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

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- **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:** CO<sub>2</sub>, sand, extinguishing powder. Do not use water.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** 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:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).  
Do not flush with water or aqueous cleansing agents
- **6.4 Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

### SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** For dental use only.
- **Information about fire - and explosion protection:** Keep ignition sources away - Do not smoke.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** See storage instructions on package
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Keep container tightly sealed.
- **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:** Wash hands before breaks and at the end of work.
- **Respiratory protection:** Not required.
- **Protection of hands:** Not required.
- **Material of gloves** Not applicable.
- **Eye protection:** Safety glasses

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### SECTION 9: Physical and chemical properties

#### · 9.1 Information on basic physical and chemical properties

##### · General Information

##### · Appearance:

|                  |                 |
|------------------|-----------------|
| Form:            | Fluid           |
| Colour:          | Colourless      |
| Odour:           | Characteristic  |
| Odour threshold: | Not determined. |

· pH-value at 20 °C: 7

##### · Change in condition

|                              |               |
|------------------------------|---------------|
| Melting point/Melting range: | Undetermined. |
| Boiling point/Boiling range: | Undetermined. |

· Flash point: 23 °C

· Flammability (solid, gaseous): Not applicable.

· Decomposition temperature: Not determined.

· Self-igniting: Product is not selfigniting.

· Danger of explosion: Product does not present an explosion hazard.

|                   |                       |
|-------------------|-----------------------|
| Density at 20 °C: | 0.9 g/cm <sup>3</sup> |
| Relative density  | Not determined.       |
| Vapour density    | Not determined.       |
| Evaporation rate  | Not determined.       |

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

· Partition coefficient (n-octanol/water): Not determined.

##### · Viscosity:

|            |                 |
|------------|-----------------|
| Dynamic:   | Not determined. |
| Kinematic: | Not determined. |

· 9.2 Other information No further relevant information available.

### SECTION 10: Stability and reactivity

· 10.1 Reactivity No further relevant information available.

· 10.2 Chemical stability

· Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

· 10.3 Possibility of hazardous reactions No dangerous reactions known.

· 10.4 Conditions to avoid No further relevant information available.

· 10.5 Incompatible materials: No further relevant information available.

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

### SECTION 11: Toxicological information

#### · 11.1 Information on toxicological effects

· Acute toxicity Based on available data, the classification criteria are not met.

· Primary irritant effect:

· Skin corrosion/irritation

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

· 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 (carcinogenicity, mutagenicity and toxicity for reproduction)

· Germ cell mutagenicity Based on available data, the classification criteria are not met.

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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.
- **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

- |                                                                                     |                                                |
|-------------------------------------------------------------------------------------|------------------------------------------------|
| · <b>14.1 UN-Number</b>                                                             | UN1170                                         |
| · <b>ADR, IMDG, IATA</b>                                                            |                                                |
| · <b>14.2 UN proper shipping name</b>                                               | -                                              |
| · <b>ADR</b>                                                                        | 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION) |
| · <b>IMDG</b>                                                                       | ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)      |
| · <b>IATA</b>                                                                       | ETHANOL SOLUTION                               |
| · <b>14.3 Transport hazard class(es)</b>                                            | -                                              |
| · <b>ADR, IMDG, IATA</b>                                                            |                                                |
|  |                                                |
| · <b>Class</b>                                                                      | 3 Flammable liquids.                           |
| · <b>Label</b>                                                                      | 3                                              |
| · <b>14.4 Packing group</b>                                                         | -                                              |
| · <b>ADR, IMDG, IATA</b>                                                            | II                                             |
| · <b>14.5 Environmental hazards:</b>                                                | Not applicable.                                |

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|                                                                                  |                                                          |
|----------------------------------------------------------------------------------|----------------------------------------------------------|
| · <b>Marine pollutant:</b>                                                       | No                                                       |
| · <b>14.6 Special precautions for user</b>                                       | Not applicable.<br>Warning: Flammable liquids.           |
| · <b>Danger code (Kemler):</b>                                                   | 33                                                       |
| · <b>EMS Number:</b>                                                             | F-E, <u>S-E</u>                                          |
| · <b>Stowage Category</b>                                                        | A                                                        |
| · <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b> | Not applicable.                                          |
| · <b>Transport/Additional information:</b>                                       |                                                          |
| · <b>ADR</b>                                                                     |                                                          |
| · <b>Limited quantities (LQ)</b>                                                 | 1L                                                       |
| · <b>Transport category</b>                                                      | 2                                                        |
| · <b>Tunnel restriction code</b>                                                 | D/E                                                      |
| · <b>UN "Model Regulation":</b>                                                  | UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, II |

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- Directive 2012/18/EU
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **Seveso category** P5c FLAMMABLE LIQUIDS
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 5,000 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 50,000 t
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

### 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  
 Flam. Liq. 2: Flammable liquids – Category 2  
 Flam. Liq. 3: Flammable liquids – Category 3  
 Acute Tox. 3: Acute toxicity – Category 3  
 Acute Tox. 4: Acute toxicity – Category 4  
 Eye Dam. 1: Serious eye damage/eye irritation – Category 1
- **\* Data compared to the previous version altered.**

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