

# Safety data sheet

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

Printing date 01.09.2015

Version number 5

Revision: 01.09.2015

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

- **1.1 Product identifier**
- **Trade name: Bifix Temp 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 luting cement
- **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**  
Eye Irrit. 2 H319 Causes serious eye irritation.  
Skin Sens. 1 H317 May cause an allergic skin reaction.
- **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 serious eye irritation.  
May cause an allergic skin reaction.
- **Precautionary statements**  
Wear protective gloves / eye protection.  
Wear protective clothing.  
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
If skin irritation or rash occurs: Get medical advice/attention.  
If eye irritation persists: Get medical advice/attention.  
IF ON SKIN: Wash with plenty of water.
- **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: 72869-86-4	Urethanedimethacrylate	5-10%
EINECS: 276-957-5	Aquatic Chronic 3, H412	
CAS: 109-16-0	Triethylene glycol dimethacrylate	5-10%
EINECS: 203-652-6	Skin Sens. 1, H317	
	Catalyst	1-2.5%
	Eye Dam. 1, H318	
	Acute Tox. 4, H302	

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**Trade name: Bifix Temp base**

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	≤ 2.5%
Catalyst	
Aquatic Acute 1, H400	
Acute Tox. 4, H302; Acute Tox. 4, H332; Skin Irrit. 2, H315; Eye Irrit. 2, H319	

#### **SECTION 4: First aid measures**

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

#### **SECTION 5: Firefighting measures**

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

#### **SECTION 6: Accidental release measures**

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

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Trade name: *Bifix Temp base*

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- **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:**
- 
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:**
- |   |   |
|---|---|
| <b>Form:</b>                                    | Pasty   |
| <b>Colour:</b>                                  | Cream coloured                                |
| <b>Odour:</b>                                   | Characteristic                                |
| <b>Odour threshold:</b>                         | Not determined.                               |
| <b>pH-value:</b>                                | Not determined.                               |
| <b>Change in condition</b>                      |   |
| <b>Melting point/Melting range:</b>             | Undetermined.                                 |
| <b>Boiling point/Boiling range:</b>             | Undetermined.                                 |
| <b>Flash point:</b>                             | 101 °C  |
| <b>Flammability (solid, gaseous):</b>           | Not applicable.                               |
| <b>Decomposition temperature:</b>               | Not determined.                               |
| <b>Self-igniting:</b>                           | Product is not selfigniting.                  |
| <b>Danger of explosion:</b>                     | Product does not present an explosion hazard. |
| <b>Density:</b>                                 | Not determined.                               |
| <b>Relative density</b>                         | Not determined.                               |
| <b>Vapour density</b>                           | Not determined.                               |
| <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.                               |

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**Trade name: Bifix Temp base**

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· **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**
- **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**  
*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** *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.*

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

### SECTION 14: Transport information

- |  |                 |
|--|-----------------|
| · <b>14.1 UN-Number</b>  |                 |
| · <b>ADR, ADN, IMDG, IATA</b>  | Void            |
| · <b>14.2 UN proper shipping name</b>  | -               |
| · <b>ADR, ADN, IMDG, IATA</b>  | Void            |
| · <b>14.3 Transport hazard class(es)</b>   | -               |
| · <b>ADR, ADN, IMDG, IATA</b>  |                 |
| · <b>Class</b>   | Void            |
| · <b>14.4 Packing group</b>  | -               |
| · <b>ADR, IMDG, IATA</b>   | Void            |
| · <b>14.5 Environmental hazards:</b>   |                 |
| · <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. |
| · <b>UN "Model Regulation":</b>  | -               |

### 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 MSDS:** 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
  - Acute Tox. 4 Acute toxicity, Hazard Category 4
  - Skin Irrit. 2 Skin corrosion/irritation, Hazard Category 2
  - Eye Dam. 1 Serious eye damage/eye irritation, Hazard Category 1
  - Eye Irrit. 2 Serious eye damage/eye irritation, Hazard Category 2
  - Skin Sens. 1 Sensitisation - Skin, Hazard Category 1
  - Aquatic Acute 1 Hazardous to the aquatic environment - Acute Hazard, Category 1
  - Aquatic Chronic 3 Hazardous to the aquatic environment - Chronic Hazard, Category 3
- **\* Data compared to the previous version altered.**

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- **1.1 Product identifier**
- **Trade name: *Bifix Temp 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 luting cement
- **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 Sens. 1 H317 May cause an allergic skin reaction.*
- **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**  
*May cause an allergic skin reaction.*
- **Precautionary statements**  
*Wear protective gloves / protective clothing.  
If skin irritation or rash occurs: Get medical advice/attention.  
IF ON SKIN: Wash with plenty of water.*
- **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: 109-16-0 EINECS: 203-652-6	Triethylene glycol dimethacrylate	Skin Sens. 1, H317	5-10%
CAS: 72869-86-4 EINECS: 276-957-5	Urethanedimethacrylate	Aquatic Chronic 3, H412	5-10%
	benzoyl peroxyde	Org. Perox. B, H241 Eye Irrit. 2, H319; Skin Sens. 1, H317	≤ 2.5%

### SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:** Seek medical treatment in case of complaints.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **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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**Trade name: Bifix Temp catalyst**

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

### SECTION 6: Accidental release measures

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



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

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application.  
· **Eye protection:** Not required.

### SECTION 9: Physical and chemical properties

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

##### · General Information

##### · Appearance:

· <b>Form:</b>	Pasty
· <b>Colour:</b>	Transparent
· <b>Odour:</b>	Characteristic
· <b>Odour threshold:</b>	Not determined.

· <b>pH-value:</b>	Not determined.
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##### · Change in condition

· <b>Melting point/Melting range:</b>	Undetermined.
· <b>Boiling point/Boiling range:</b>	Undetermined.

· <b>Flash point:</b>	101 °C
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· <b>Flammability (solid, gaseous):</b>	Not applicable.
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· <b>Decomposition temperature:</b>	Not determined.
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· <b>Self-igniting:</b>	Product is not selfigniting.
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· <b>Danger of explosion:</b>	Product does not present an explosion hazard.
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· <b>Density:</b>	Not determined.
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· <b>Relative density</b>	Not determined.
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· <b>Vapour density</b>	Not determined.
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· <b>Evaporation rate</b>	Not determined.
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##### · Solubility in / Miscibility with water:

Not miscible or difficult to mix.

· <b>Partition coefficient (n-octanol/water):</b>	Not determined.
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##### · Viscosity:

· <b>Dynamic:</b>	Not determined.
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· <b>Kinematic:</b>	Not determined.
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· <b>9.2 Other information</b>	No further relevant information available.
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### 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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### SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity**
- **Primary irritant effect:**
- **Skin corrosion/irritation**  
*Testing according to ISO 10993-1/10993-10 showed no skin irritation for this product when fully cured*
- **Serious eye damage/irritation** *Based on available data, the classification criteria are not met.*
- **Respiratory or skin sensitisation**  
*May cause an allergic skin reaction.*
- **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** *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>                  | <i>Attention: special provisions A197 IATA, 375 ADR and/or IMDG-Code paragraph 2.10.2.7 may be applied during transport.</i> |
| · <b>14.2 UN proper shipping name</b>    | -  |
| · <b>14.3 Transport hazard class(es)</b> | -  |
| · <b>14.4 Packing group</b>              | -  |

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- |  |                 |
|--|-----------------|
| · <b>14.5 Environmental hazards:</b>   |                 |
| · <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.

**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 MSDS:** 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)  
 PBT Persistent, Bioaccumulative and Toxic  
 vPvB very Persistent and very Bioaccumulative  
 Org. Perox. B Organic Peroxides, Type B  
 Eye Irrit. 2 Serious eye damage/eye irritation, Hazard Category 2  
 Skin Sens. 1 Sensitisation - Skin, Hazard Category 1  
 Aquatic Chronic 3 Hazardous to the aquatic environment - Chronic Hazard, Category 3
- **\* Data compared to the previous version altered.**

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