

# Safety data sheet

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

Printing date 03.06.2020

Version: 5

Revision: 03.06.2020

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

- **1.1 Product identifier**
- **Trade name:** Alphalink Implant
- **Article number:** 640076
- **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 Cement
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Schütz Dental GmbH, Dieselstrasse 5-6, D-61191 Rosbach v.d.H. (Germany)  
Tel.: +49 (0)6003/814-0 Fax: +49 (0)6003/814-900  
www.schuetz-dental.de; e-mail: info@schuetz-dental.de
- **Further information obtainable from:** F&E, Tel. +49 (0)6003/814-100
- **1.4 Emergency telephone number:**  
+49 (0) 6003 8140 Schütz Dental (8:00 - 17:00 Uhr) or  
+49 (0) 6131 19240 Poison Information Center, University Mainz (24 h)


### SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
The product is not classified, according to the CLP regulation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Additional information:**  
Contains dibenzoyl peroxide. May produce an allergic reaction.  
Safety data sheet available on request.
- **Labelling of packages where the contents do not exceed 125 ml**
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Adhesive material for dental use.

· **Dangerous components:**

63225-53-6	2-[[[(butylamino)carbonyl]oxy]ethyl acrylate	2.5-10%
	 Skin Irrit. 2, H315; Eye Irrit. 2, H319	

- **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** Supply fresh air; consult doctor in case of complaints.
- **After skin contact** If skin irritation continues, consult a doctor.
- **After eye contact** Rinse opened eye for several minutes under running water.

(Contd. on page 2)

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(Contd. of page 1)

- **After swallowing**  
Rinse out mouth and then drink plenty of water.  
Call a doctor immediately.
- **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.
- **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:** Adapt to environment.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Avoid eye and skin contact with the substance.
- **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**  
No dangerous substances are released.  
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** Keep away from heat and direct sunlight.
- **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:** Store in refrigerator.
- **Information about storage in one common storage facility:** Store away from foodstuffs.
- **Further information about storage conditions:** None.
- **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.

(Contd. on page 3)

# Safety data sheet

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(Contd. of page 2)

- **Respiratory protection:** Not necessary if room is well-ventilated.
- **Protection of hands:** Solvent resistant gloves
- **Material of gloves**  
Butyl rubber, BR  
Nitrile rubber, NBR
- **Penetration time of glove material**  
0,3 mm  
Penetration time 60 min.  
0,11 mm  
Penetration time 10 min.
- **Eye protection:** Goggles recommended during refilling.
- **Body protection:** Protective work clothing.

### SECTION 9: Physical and chemical properties

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

##### · General Information

##### · Appearance:

<b>Form:</b>	Viscous
<b>Colour:</b>	Colourless
<b>Odour:</b>	Weak, characteristic
<b>Odour threshold:</b>	Not determined.

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

<b>Melting point/freezing point:</b>	undetermined
<b>Initial boiling point and boiling range:</b>	251 °C

· <b>Flash point:</b>	151 °C
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· <b>Flammability (solid, gaseous)</b>	Not applicable.
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· <b>Ignition temperature:</b>	400 °C
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· <b>Decomposition temperature:</b>	Not determined.
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· <b>Auto-ignition temperature:</b>	Product is not selfigniting.
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· <b>Explosive properties:</b>	Product does not present an explosion hazard.
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##### · Explosion limits:

<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.

· <b>Vapour pressure:</b>	1,3 mbar (110 °C) Not determined.
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· <b>Density:</b>	Not determined
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.

##### · Solubility in / Miscibility with

<b>Water:</b>	Not miscible or difficult to mix
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· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
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##### · Viscosity:

<b>dynamic:</b>	Not determined.
<b>kinematic:</b>	Not determined.

##### · Solvent content:

<b>Solids content:</b>	0.0 %
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(Contd. on page 4)

**Trade name: Alphalink Implant**

(Contd. of page 3)

## 9.2 Other information

*No further relevant information available.*

## SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** Exothermic polymerization
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:**  
In presence of radical formers (e. g. peroxides), deoxidizing substances, and/or heavy metal ions, polymerization with heat release is possible.
- **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:***  
     dibenzoyl peroxide: 78 % in water   oral                 > 5000 mg/kg   rat  
                                 inhalation   > 24,3 mg/1/4h   rat
- N,N-Bis(2-hydroxyethyl)-p-toluidine   LD-50 oral         300 mg/kg rat
- ***Primary irritant effect:***
- ***Skin corrosion/irritation*** Based on available data, the classification criteria are not met.
- ***Serious eye damage/irritation*** Based on available data, the classification criteria are not met.
- ***Respiratory or skin sensitisation*** Based on available data, the classification criteria are not met.
- ***CMR effects (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 2 (German Regulation) (Self-assessment): hazardous for water.  
Do not allow product to reach ground water, water course or sewage system.  
Danger to drinking water if even small quantities leak into the ground.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

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(Contd. of page 4)

### SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation** Must be specially treated adhering to official regulations.

- **European waste catalogue**

08 04 10	waste adhesives and sealants other than those mentioned in 08 04 09
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- **Uncleaned packaging:**
- **Recommendation:**  
Empty contaminated packagings thoroughly. They may be recycled after thorough and proper cleaning. Packagings that may not be cleansed are to be disposed of in the same manner as the product.
- **Recommended cleansing agents:** Ethyl acetate

### SECTION 14: Transport information

- |   |                 |
|---|-----------------|
| <ul style="list-style-type: none"> <li>· <b>14.1 UN-Number</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> </ul>  | Void            |
| <ul style="list-style-type: none"> <li>· <b>14.2 UN proper shipping name</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> </ul>                            | Void            |
| <ul style="list-style-type: none"> <li>· <b>14.3 Transport hazard class(es)</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> <li>· <b>Class</b></li> </ul> | Void            |
| <ul style="list-style-type: none"> <li>· <b>14.4 Packing group</b></li> <li>· <b>ADR, IMDG, IATA</b></li> </ul>   | Void            |
| <ul style="list-style-type: none"> <li>· <b>14.5 Environmental hazards:</b></li> <li>· <b>Marine pollutant:</b></li> </ul>                                | No              |
| <ul style="list-style-type: none"> <li>· <b>14.6 Special precautions for user</b></li> </ul>  | Not applicable. |
| <ul style="list-style-type: none"> <li>· <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b></li> </ul>                        | Not applicable. |
| <ul style="list-style-type: none"> <li>· <b>UN "Model Regulation":</b></li> </ul>   | Void            |

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **National regulations**
- **Waterhazard class:** Water hazard class 2 (Self-assessment): hazardous for water.
- **15.2 Chemical safety assessment:** 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.

- **Relevant phrases**  
H315 Causes skin irritation.  
H319 Causes serious eye irritation.
- **Department issuing SDS:** F & E

(Contd. on page 6)

GB

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(Contd. of page 5)

· **Contact:** Dr. U. Krichbaum

· **Abbreviations and acronyms:**

*RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)*

*ICAO: International Civil Aviation Organisation*

*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)*

*LC50: Lethal concentration, 50 percent*

*LD50: Lethal dose, 50 percent*

*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*

· **\* Data compared to the previous version altered.**

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