

**Safety Data Sheet**

according to UK REACH Regulation

**Alphalink Implant**

Revision date: 05.08.2024

Product code: 640076

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**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

Alphalink Implant

**Further trade names**

Art.-Nr. 640076

**1.2. Relevant identified uses of the substance or mixture and uses advised against****Use of the substance/mixture**

Dental Cement

**1.3. Details of the supplier of the safety data sheet**

Company name:	Schütz Dental GmbH	
Street:	Dieselstrasse 5-6	
Place:	D-61191 Rosbach (Germany)	
Telephone:	+49 (0) 6003 814-0	Telefax: +49 (0) 6003 814-906
E-mail:	info@schuetz-dental.de	
Contact person:	Dr. Uwe Krichbaum	Telephone: +49 (0) 6003 814-650
Internet:	www.schuetz-dental.de	
Responsible Department:	Technische Dokumentation	

**1.4. Emergency telephone number:** +49 (0) 6003 814-0 Schütz Dental (8:00 - 17:00 Uhr) or +49 (0) 6131 19240 University Mainz (24 h)

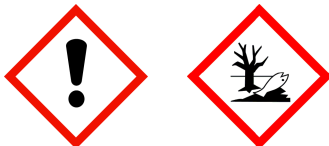
**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture****GB CLP Regulation**

Skin Sens. 1; H317  
 Aquatic Chronic 2; H411

Full text of hazard statements: see SECTION 16.

**2.2. Label elements****GB CLP Regulation****Hazard components for labelling**

di-urethane dimethacrylate  
 2-[[[butylamino)carbonyl]oxy]ethyl acrylate  
 dibenzoyl peroxide

**Signal word:** Warning**Pictograms:****Hazard statements**

H317 May cause an allergic skin reaction.  
 H332 Harmful if inhaled.  
 H411 Toxic to aquatic life with long lasting effects.

**Precautionary statements**

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.  
 P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.  
 P312 Call a POISON CENTER if you feel unwell.  
 P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

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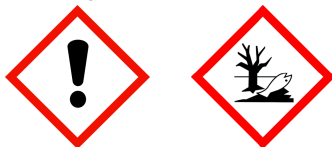
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P501 Dispose of contents/container to Dispose of waste according to applicable legislation..

**Labelling of packages where the contents do not exceed 125 ml**

Signal word: Warning

Pictograms:

**Hazard statements**

H317

**Precautionary statements**

P261-P280-P501

**2.3. Other hazards**

No information available.

**SECTION 3: Composition/information on ingredients****3.2. Mixtures****Relevant ingredients**

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (GB CLP Regulation)			
41137-60-4	di-urethane dimethacrylate			25 - < 50 %
	Skin Sens. 1B, Aquatic Chronic 2; H317 H411			
63225-53-6	2-[[[(butylamino)carbonyl]oxy]ethyl acrylate			2.5 - < 10 %
	Acute Tox. 4, Skin Sens. 1A, Aquatic Chronic 2; H332 H317 H411			
94-36-0	dibenzoyl peroxide			< 2.5 %
	202-327-6	617-008-00-0		
	Org. Perox. B, Eye Irrit. 2, Skin Sens. 1, Aquatic Chronic 1; H241 H319 H317 H410			

Full text of H and EUH statements: see section 16.

**Specific Conc. Limits, M-factors and ATE**

CAS No	EC No	Chemical name	Quantity
	Specific Conc. Limits, M-factors and ATE		
63225-53-6		2-[[[(butylamino)carbonyl]oxy]ethyl acrylate	2.5 - < 10 %
	inhalation: ATE = 11 mg/l (vapours); inhalation: ATE = 1,5 mg/l (dusts or mists)		

**SECTION 4: First aid measures****4.1. Description of first aid measures****After inhalation**

Provide fresh air. When in doubt or if symptoms are observed, get medical advice.

**After contact with skin**

After contact with skin, wash immediately with plenty of water and soap. In case of skin irritation, consult a physician.

**After contact with eyes**

Rinse immediately carefully and thoroughly with eye-bath or water. In case of eye irritation consult an ophthalmologist.

**After ingestion**

Rinse mouth immediately and drink 1 glass of water. Call a physician immediately.

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### **4.2. Most important symptoms and effects, both acute and delayed**

No information available.

### **4.3. Indication of any immediate medical attention and special treatment needed**

Treat symptomatically.

## **SECTION 5: Firefighting measures**

### **5.1. Extinguishing media**

#### **Suitable extinguishing media**

Co-ordinate fire-fighting measures to the fire surroundings.

Water spray jet

Carbon dioxide (CO<sub>2</sub>)

Extinguishing powder

#### **Unsuitable extinguishing media**

Full water jet

### **5.2. Special hazards arising from the substance or mixture**

Non-flammable.

### **5.3. Advice for firefighters**

No special measures are necessary.

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

### **6.1. Personal precautions, protective equipment and emergency procedures**

#### **General advice**

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

### **6.2. Environmental precautions**

Do not allow to enter into surface water or drains.

### **6.3. Methods and material for containment and cleaning up**

#### **For cleaning up**

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

### **6.4. Reference to other sections**

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

## **SECTION 7: Handling and storage**

### **7.1. Precautions for safe handling**

#### **Advice on safe handling**

No special measures are necessary.

#### **Advice on protection against fire and explosion**

No special fire protection measures are necessary.

### **7.2. Conditions for safe storage, including any incompatibilities**

#### **Requirements for storage rooms and vessels**

Keep container tightly closed. Store in a fire-resistant refrigerator.

#### **Hints on joint storage**

No special measures are necessary.

### **7.3. Specific end use(s)**

Dental Cement

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### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

##### Exposure limits (EH40)

CAS No	Substance	ppm	mg/m <sup>3</sup>	fibres/ml	Category	Origin
94-36-0	Dibenzoyl peroxide	-	5		TWA (8 h)	WEL
60676-86-0	Silica, fused respirable dust	-	0.08		TWA (8 h)	WEL

#### 8.2. Exposure controls



#### Individual protection measures, such as personal protective equipment

##### Eye/face protection

Wear eye protection/face protection.

##### Hand protection

Tested protective gloves must be worn

Butyl caoutchouc (butyl rubber)

NBR (Nitrile rubber)

Permeation time (maximum wear duration): 0,3 mm: 60 min.

Permeation time (maximum wear duration): 0,11 mm: 10 min.

##### Skin protection

Use of protective clothing.

##### Respiratory protection

Usually no personal respirative protection necessary.

### SECTION 9: Physical and chemical properties

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

Physical state:

Colour: colourless

Melting point/freezing point:

not determined

Boiling point or initial boiling point and

251 °C

boiling range:

Flammability:

not determined

Lower explosion limits:

not determined

Upper explosion limits:

not determined

Flash point:

151 °C

Auto-ignition temperature:

not determined

Decomposition temperature:

not determined

pH-Value:

not determined

Viscosity / kinematic:

not determined

Water solubility:

No

Solubility in other solvents

not determined

Partition coefficient n-octanol/water:

not determined

Vapour pressure:

not determined

Density:

not determined

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Relative vapour density:

not determined

Particle characteristics:

not applicable

**9.2. Other information****Information with regard to physical hazard classes**

Explosive properties

The product is not: Explosive.

Oxidizing properties

The product is not: oxidising.

**Other safety characteristics**

Solid content:

0 %

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

No hazardous reaction when handled and stored according to provisions.

**10.2. Chemical stability**

The product is stable under storage at normal ambient temperatures.

**10.3. Possibility of hazardous reactions**

Hazardous polymerisation:

**10.4. Conditions to avoid**

none

**10.5. Incompatible materials**

Polymerization with heat evolution may occur in the presence of radical forming substances (e.g. peroxides), reducing substances, and/or heavy metal ions.

**10.6. Hazardous decomposition products**

No known hazardous decomposition products.

**SECTION 11: Toxicological information****11.1. Information on hazard classes as defined in GB CLP Regulation****Acute toxicity**

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

**ATEmix calculated**

ATE (oral) &gt; 2000 mg/kg; ATE (dermal) &gt; 2000 mg/kg; ATE (inhalation vapour) &gt; 20 mg/l; ATE (inhalation dust/mist) &gt; 5 mg/l

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
63225-53-6	2-[[[(butylamino)carbonyl]oxy]ethyl acrylate				
	inhalation vapour	ATE 11 mg/l			
	inhalation dust/mist	ATE 1,5 mg/l			

**Irritation and corrosivity**

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation: Based on available data, the classification criteria are not met.

**Sensitising effects**

May cause an allergic skin reaction. (di-urethane dimethacrylate; 2-[[[(butylamino)carbonyl]oxy]ethyl acrylate; dibenzoyl peroxide)

**Carcinogenic/mutagenic/toxic effects for reproduction**

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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.

## 11.2. Information on other hazards

### Other information

The mixture is classified as hazardous according to regulation (EC) No 1272/2008 [CLP].

## SECTION 12: Ecological information

### 12.1. Toxicity

Toxic to aquatic life with long lasting effects.

Toxic to aquatic life with long lasting effects.

### 12.2. Persistence and degradability

The product has not been tested.

### 12.3. Bioaccumulative potential

The product has not been tested.

### 12.4. Mobility in soil

The product has not been tested.

### 12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to UK REACH.

The product has not been tested.

### 12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

### 12.7. Other adverse effects

No information available.

### Further information

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

#### Disposal recommendations

Do not allow to enter into surface water or drains. Dispose of waste according to applicable legislation.

#### Contaminated packaging

Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself.

## SECTION 14: Transport information

### Land transport (ADR/RID)

#### 14.1. UN number or ID number:

UN 3082

#### 14.2. UN proper shipping name:

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
di-urethane dimethacrylate, 2-[[[butylamino)carbonyl]oxy]ethyl acrylate

#### 14.3. Transport hazard class(es):

9

#### 14.4. Packing group:

III

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Hazard label:

9



Classification code:

M6

Special Provisions:

274 335 375 601

Limited quantity:

5 L

Excepted quantity:

E1

Transport category:

3

Hazard No:

90

Tunnel restriction code:

-

**Inland waterways transport (ADN)****14.1. UN number or ID number:**

UN 3082

**14.2. UN proper shipping name:**

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.

**14.3. Transport hazard class(es):**

9

**14.4. Packing group:**

III

Hazard label:

9



Classification code:

M6

Special Provisions:

274 335 375 601

Limited quantity:

5 L

Excepted quantity:

E1

**Marine transport (IMDG)****14.1. UN number or ID number:**

UN 3082

**14.2. UN proper shipping name:**ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,  
N.O.S.di-urethane dimethacrylate, 2-[[[(butylamino)carbonyl]oxy]ethyl  
acrylate**14.3. Transport hazard class(es):**

9

**14.4. Packing group:**

III

Hazard label:

9



Special Provisions:

274 335 969

Limited quantity:

5 L

Excepted quantity:

E1

EmS:

F-A, S-F

**Air transport (ICAO-TI/IATA-DGR)****14.1. UN number or ID number:**

UN 3082

**14.2. UN proper shipping name:**

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.

**14.3. Transport hazard class(es):**

9

**14.4. Packing group:**

III

Hazard label:

9



Special Provisions:

A97 A158 A197 A215

Limited quantity Passenger:

30 kg G

Passenger LQ:

Y964

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Excepted quantity:	E1	
IATA-packing instructions - Passenger:		964
IATA-max. quantity - Passenger:		450 L
IATA-packing instructions - Cargo:		964
IATA-max. quantity - Cargo:		450 L

**14.5. Environmental hazards**

ENVIRONMENTALLY HAZARDOUS: No

**14.6. Special precautions for user**

No information available.

**14.7. Maritime transport in bulk according to IMO instruments**

not applicable

**Other applicable information**

Hazchem code: •3Z

**SECTION 15: Regulatory information****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****EU regulatory information**

Restrictions on use (REACH, annex XVII):

Entry 3, Entry 75

Information according to Directive 2012/18/EU (SEVESO III):

E2 Hazardous to the Aquatic Environment

**National regulatory information**

Employment restrictions:

Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC).

Water hazard class (D):

2 - obviously hazardous to water

Skin resorption/Sensitization:

Causes allergic hypersensitivity reactions.

**15.2. Chemical safety assessment**

Chemical safety assessments for substances in this mixture were not carried out.

**SECTION 16: Other information****Changes**

This data sheet contains changes from the previous version in section(s): 4,5,7,8,10,13,14.



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**Abbreviations and acronyms**

Org. Perox

Acute Tox: Acute toxicity

Eye Irrit: Eye irritation

Skin Sens: Skin sensitisation

Aquatic Chronic: Chronic aquatic hazard

CLP: Classification, labelling and Packaging

REACH: Registration, Evaluation and Authorization of Chemicals

GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals

UN: United Nations

EC/EEC: European Community/European Economic Community

EU: European Union

CAS: Chemical Abstracts Service

DNEL: Derived No Effect Level

DMEL: Derived Minimal Effect Level

PNEC: Predicted No Effect Concentration

ATE: Acute toxicity estimate

LC50: Lethal concentration, 50%

LD50: Lethal dose, 50%

LL50: Lethal loading, 50%

EL50: Effect loading, 50%

EC50: Effective Concentration 50%

ErC50: Effective Concentration 50%, growth rate

NOEC: No Observed Effect Concentration

BCF: Bio-concentration factor

PBT: persistent, bioaccumulative, toxic

vPvB: very persistent, very bioaccumulative

M-factor: Multiplying factor

ADR: Accord européen sur le transport des marchandises dangereuses par Route  
(European Agreement concerning the International Carriage of Dangerous Goods by Road)

RID: Regulations concerning the international carriage of dangerous goods by rail

MARPOL: International Convention for the Prevention of Marine Pollution from Ships

IBC: Intermediate Bulk Container

SVHC: Substance of Very High Concern

For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).

**Classification for mixtures and used evaluation method according to GB CLP Regulation**

Classification	Classification procedure
Skin Sens. 1; H317	Calculation method
Aquatic Chronic 2; H411	Calculation method

**Relevant H and EUH statements (number and full text)**

H241	Heating may cause a fire or explosion.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.

**Further Information**

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

*(The data for the relevant ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)*