

Safety Data Sheet

according to UK REACH Regulation

Alphalink Cem

Revision date: 05.08.2024

Product code: 639012

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

Alphalink Cem

Further trade names

Art.-Nr.: 639012, 639014

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

Adhesive material for dental use

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 3; H412

Full text of hazard statements: see SECTION 16.

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

di-urethane dimethacrylate
 tetramethylene dimethacrylate
 dibenzoyl peroxide

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

H317 May cause an allergic skin reaction.
 H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
 P273 Avoid release to the environment.
 P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
 P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
 P501 Dispose of contents/container to Dispose of waste according to applicable legislation..

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Labelling of packages where the contents do not exceed 125 ml

Signal word: Warning

Pictograms:

**Hazard statements**

H317-H412

Precautionary statements

P261-P280-P333+P313-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 | | | 10 - < 25 % |
| | Skin Sens. 1B, Aquatic Chronic 2; H317 H411 | | | |
| 2082-81-7 | tetramethylene dimethacrylate | | | 2.5 - < 10 % |
| | 218-218-1 | 607-134-00-4 | | |
| | Skin Sens. 1B; H317 | | | |
| 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.

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. Take off immediately all contaminated clothing and wash it before reuse. 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.

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.

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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 (CO₂)
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

Wear a self-contained breathing apparatus and chemical protective clothing. Full protection suit.

Additional information

Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately.
Do not allow entering drains or surface water.

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

Take up mechanically. 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.

Advice on general occupational hygiene

Remove contaminated, saturated clothing immediately.

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 restriction

7.3. Specific end use(s)

Adhesive material for dental use

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits (EH40)

| CAS No | Substance | ppm | mg/m ³ | fibres/ml | Category | Origin |
|---------|--------------------|-----|-------------------|-----------|-----------|--------|
| 94-36-0 | Dibenzoyl peroxide | - | 5 | | 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

In case of inadequate ventilation wear respiratory protection.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:

Colour:

Melting point/freezing point:

< - 20 °C

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:

113 °C

Auto-ignition temperature:

> 370 °C

Decomposition temperature:

not determined

pH-Value:

not determined

Viscosity / kinematic:

not applicable

Water solubility:

No

Solubility in other solvents

not determined

Partition coefficient n-octanol/water:

not determined

Vapour pressure:

not determined

Density:

not determined

Relative vapour density:

not determined

Particle characteristics:

not determined

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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) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 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; tetramethylene dimethacrylate; dibenzoyl peroxide)

Carcinogenic/mutagenic/toxic effects 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.

11.2. Information on other hazards

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Other information

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

SECTION 12: Ecological information

12.1. Toxicity

Harmful to aquatic life with long lasting effects.

Harmful 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:

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es):

No dangerous good in sense of this transport regulation.

14.4. Packing group:

No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)

14.1. UN number or ID number:

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es):

No dangerous good in sense of this transport regulation.

14.4. Packing group:

No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

14.1. UN number or ID number:

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es):

No dangerous good in sense of this transport regulation.

14.4. Packing group:

No dangerous good in sense of this transport regulation.

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Air transport (ICAO-TI/IATA-DGR)

| | |
|--|--|
| 14.1. UN number or ID number: | No dangerous good in sense of this transport regulation. |
| 14.2. UN proper shipping name: | No dangerous good in sense of this transport regulation. |
| 14.3. Transport hazard class(es): | No dangerous good in sense of this transport regulation. |
| 14.4. Packing group: | No dangerous good in sense of this transport regulation. |

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

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 75

Information according to Directive 2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)

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): 1 - slightly 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): 1,2,4,5,7,8,9,10,13,14.

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Abbreviations and acronyms

Org. Perox

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 3; H412 | 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. |
| H410 | Very toxic to aquatic life with long lasting effects. |
| H411 | Toxic to aquatic life with long lasting effects. |
| H412 | Harmful 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.)