

**Safety data sheet**  
**according to 1907/2006/EC, Article 31**

Page 1/6

Printing date 29.11.2022

Revision: 28.11.2022

**1 Identification of the substance/mixture and of the company/undertaking**

- **Product identifier**
- **Trade name:** Alginoplast SH
- **Article number:** 66096906
- **UFI:** SJG0-D05C-X004-EH7G
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** Dental.
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Cavex Holland B.V.  
Nederland
  
- Kulzer GmbH  
Leipziger Straße 2, 63450 Hanau (Germany)  
Tel.: +49 (0)800 4372522  
E-Mail: msds@kulzer-dental.com
- **Further information obtainable from:** Product safety department
- **Emergency telephone number:** Emergency CONTACT (24-Hour-Number): +49 (0)6132-84463

**2 Hazards identification**

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
The product is not classified, according to the CLP regulation.
- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Labelling of packages where the contents do not exceed 125 ml**
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

**3 Composition/information on ingredients**

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

**Dangerous components:**

|                                      |                                                                                                                                |          |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|----------|
| CAS: 68855-54-9<br>EINECS: 272-489-0 | Kieselguhr, soda ash flux-calcined<br>substance with a Community workplace exposure limit                                      | 50-70%   |
| CAS: 14807-96-6<br>EINECS: 238-877-9 | Talc (Mg <sub>3</sub> H <sub>2</sub> (SiO <sub>3</sub> ) <sub>4</sub> )<br>substance with a Community workplace exposure limit | 2.5-7.5% |
| CAS: 16919-27-0<br>EINECS: 240-969-9 | dipotassium hexafluorotitanate<br>☞ Eye Dam. 1, H318; ☞ Acute Tox. 4, H302; STOT SE 3, H335                                    | ≥1-≤2.5% |
| CAS: 1309-48-4<br>EINECS: 215-171-9  | magnesium oxide<br>substance with a Community workplace exposure limit                                                         | ≤2.5%    |

(Contd. on page 2)

**Trade name: Alginoplast SH**

(Contd. of page 1)

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

#### 4 First aid measures

- **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:** 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.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed**  
No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

#### 5 Firefighting measures

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

#### 6 Accidental release measures

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

#### 7 Handling and storage

- **Handling:**
- **Precautions for safe handling** No special measures required.
- **Information about fire - and explosion protection:** No special measures required.
- **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:** None.
- **Specific end use(s)** No further relevant information available.

#### 8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**

68855-54-9 Kieselguhr, soda ash flux-calcined

OEL Long-term value: 1.2 mg/m<sup>3</sup>

(Contd. on page 3)

**Trade name: Alginoplast SH**

(Contd. of page 2)

**14807-96-6 Talc ( $Mg_3H_2(SiO_3)_4$ )**

OEL Long-term value:  $10^* 0.8^{**} \text{ mg/m}^3$   
\*total inhalable \*\*respirable dust

**1309-48-4 magnesium oxide**

OEL Short-term value:  $10^{**} \text{ mg/m}^3$   
Long-term value:  $4^* 5^{**} 10^{***} \text{ mg/m}^3$   
\*respirable dust \*\*fume \*\*\*total inhalable dust

- **Additional information:** The lists valid during the making were used as basis.
- **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:**  
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.  
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.  
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **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.
- **Penetration time of glove material**  
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** Not required.

**9 Physical and chemical properties**

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

|                  |                 |
|------------------|-----------------|
| Form:            | Powder          |
| Colour:          | Pink            |
| Odour:           | Pleasant        |
| Odour threshold: | Not determined. |
- **pH-value:** Not applicable.
- **Change in condition**

|                                          |               |
|------------------------------------------|---------------|
| Melting point/freezing point:            | Undetermined. |
| Initial boiling point and boiling range: | Undetermined. |
- **Flash point:** Not applicable.
- **Flammability (solid, gas):** Not determined.
- **Decomposition temperature:** Not determined.
- **Auto-ignition temperature:** Product is not selfigniting.
- **Explosive properties:** Product does not present an explosion hazard.
- **Explosion limits:**

|        |                 |
|--------|-----------------|
| Lower: | Not determined. |
| Upper: | Not determined. |

(Contd. on page 4)

**Trade name: Alginoplast SH**

(Contd. of page 3)

· **Vapour pressure:** Not applicable.

· **Density:** Not determined.

· **Relative density** Not determined.

· **Vapour density** Not applicable.

· **Evaporation rate** Not applicable.

· **Solubility in / Miscibility with water:** Insoluble.

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

· **Viscosity:**

· **Dynamic:** Not applicable.

· **Kinematic:** Not applicable.

· **Solvent content:**

· **Solids content:** 100.0 %

· **Other information** No further relevant information available.

## 10 Stability and reactivity

· **Reactivity** No further relevant information available.

· **Chemical stability**

· **Thermal decomposition / conditions to be avoided:**

No decomposition if used according to specifications.

· **Possibility of hazardous reactions** No dangerous reactions known.

· **Conditions to avoid** No further relevant information available.

· **Incompatible materials:** No further relevant information available.

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

## 11 Toxicological information

· **Information on toxicological effects**

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

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

Oral LD50 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.

· **Additional toxicological information:**

· **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.

## 12 Ecological information

· **Toxicity**

· **Aquatic toxicity:** No further relevant information available.

· **Persistence and degradability** No further relevant information available.

(Contd. on page 5)

**Trade name: Alginoplast SH**

(Contd. of page 4)

- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **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.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

### 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation** Smaller quantities can be disposed of with household waste.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

- |                                                                             |                 |
|-----------------------------------------------------------------------------|-----------------|
| · <b>UN-Number</b>                                                          |                 |
| · <b>ADR, ADN, IMDG, IATA</b>                                               | not regulated   |
| · <b>UN proper shipping name</b>                                            |                 |
| · <b>ADR, ADN, IMDG, IATA</b>                                               | not regulated   |
| · <b>Transport hazard class(es)</b>                                         |                 |
| · <b>ADR, ADN, IMDG, IATA</b>                                               |                 |
| · <b>Class</b>                                                              | not regulated   |
| · <b>Packing group</b>                                                      |                 |
| · <b>ADR, IMDG, IATA</b>                                                    | not regulated   |
| · <b>Environmental hazards:</b>                                             | Not applicable. |
| · <b>Special precautions for user</b>                                       | Not applicable. |
| · <b>Transport in bulk according to Annex II of Marpol and the IBC Code</b> | Not applicable. |
| · <b>UN "Model Regulation":</b>                                             | not regulated   |

### 15 Regulatory information

- **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.
- **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**  
None of the ingredients is listed.

(Contd. on page 6)

**Trade name: Alginoplast SH**

(Contd. of page 5)

· **REGULATION (EU) 2019/1148**

· **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

None of the ingredients is listed.

· **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

None of the ingredients is listed.

· **Regulation (EC) No 273/2004 on drug precursors**

None of the ingredients is listed.

· **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

None of the ingredients is listed.

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

## 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**

H302 Harmful if swallowed.

H318 Causes serious eye damage.

H335 May cause respiratory irritation.

· **Department issuing SDS:** Product safety department

· **Contact:** .

· **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)

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

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

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3