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

Printing date 26.10.2017 Version number 1 Revision: 26.10.2017

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

- · 1.1 Product identifier
  - · Trade name: Alginoplast Cream Fast, Alginoplast Cream Normal
- 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 impression material
- · 1.3 Details of the supplier of the safety data sheet
  - · Manufacturer/Supplier:

Kulzer GmbH

Leipziger Straße 2, 63450 Hanau (Germany)

au (Germany) Tel.: +49 (0)800 4372522

- · Informing department: E-Mail: msds@kulzer-dental.com
- · 1.4 Emergency telephone number: Emergency CONTACT (24-Hour-Number): +49 (0)6132-84463

## 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.

- · 2.2 Label elements
  - · Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

Hazard pictograms



GHS07

- · Signal word Warning
- · Hazard statements

H319 Causes serious eye irritation.

· Precautionary statements

P264 Wash thoroughly after handling. P280 Wear eye protection / face protection.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove

contact lenses, if present and easy to do. Continue rinsing.

P337+P313 If eye irritation persists: Get medical advice/attention.

· 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: -
  - · Dangerous components:

CAS: 16919-27-0 dipotassium hexafluorotitanate

0-5%

EINECS: 240-969-9 Eye Dam. 1, H318; Acute Tox. 4, H302; STOT SE 3, H335

Additional information
The hazards in Chapters 3 do not relate to the product itself, but to the ingredients of the product.
For more details see chapter 11.

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For the wording of the listed hazard phrases refer to section 16.

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#### SECTION 4: First aid measures

- · 4.1 Description of first aid measures
  - After inhalation Supply fresh air; consult doctor in case of symptoms.
     After skin contact If skin irritation continues, consult a doctor.

  - After eye contact

Rinse opened eye for several minutes under running water. If symptoms persist, consult doctor.

After swallowing

Rinse out mouth and then drink plenty of water.

In case of persistent symptoms 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

CO2, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.

5.2 Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

- · 5.3 Advice for firefighters
  - Protective equipment: No special measures required.
  - · Additional information -

### SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

- · 6.2 Environmental precautions: No special measures required.
- · 6.3 Methods and material for containment and cleaning up:

Send for recovery or disposal in suitable containers.

· 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 information on disposal.

# SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

Wear protective equipment. Keep unprotected persons away. Ensure good ventilation/exhaustion at the workplace.

- Information about protection against explosions and fires: No special measures required.
- · 7.2 Conditions for safe storage, including any incompatibilities
  - - Requirements to be met by storerooms and containers: No special requirements.
    - Information about storage in one common storage facility: Not required.
    - Further information about storage conditions: None.

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· 7.3 Specific end use(s) No further relevant information available.

## SECTION 8: Exposure controls/personal protection

- · Additional information about design of technical systems: No further data; see item 7.
- · 8.1 Control parameters
  - · Components with critical values that require monitoring at the workplace:

#### 8002-74-2 Paraffin waxes and Hydrocarbon waxes

WEL Short-term value: 6 mg/m³ Long-term value: 2 mg/m³

· Additional information: The lists that were valid during the compilation were used as basis.

- · 8.2 Exposure controls
  - Personal protective equipment
    - · General protective and hygienic measures

Instantly remove any soiled and impregnated garments.

Wash hands during breaks and at the end of the work.

- · Breathing equipment: Not required.
- Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

If skin contact cannot be avoided, protective gloves are recommended to avoid possible sensitization.

Check protective gloves prior to each use for their proper condition. recommended

· 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 trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:

Butyl rubber, BR Nitrile rubber, NBR

- · Eye protection: Safety glasses
- · Body protection: Light weight protective clothing

### SECTION 9: Physical and chemical properties

- · 9.1 Information on basic physical and chemical properties
  - · General Information

Appearance: Form:

· Colour:

Pasty

Different according to colour

· Smell: · Odour threshold: Sweetish Not determined.

· pH-value: Not determined.

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# Trade name: Alginoplast Cream Fast, Alginoplast Cream Normal

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Change in condition  Melting point/freezing point: Initial boiling point and boiling	Not determined range: Not determined	
· Flash point:	Not applicable	
· Inflammability (solid, gaseous)	Not applicable.	
· Ignition temperature:		
Decomposition temperature:	Not determined.	
· Self-inflammability:	Product is not selfigniting.	
Explosive properties:	Product is not explosive.	
<ul> <li>Critical values for explosion:</li> <li>Lower:</li> <li>Upper:</li> </ul>	Not determined. Not determined.	
· Steam pressure:	Not determined.	
<ul> <li>Density</li> <li>Relative density</li> <li>Vapour density</li> <li>Evaporation rate</li> </ul>	Not determined Not determined. Not determined. Not determined.	
· Solubility in / Miscibility with · Water:	Not miscible or difficult to mix	
· Partition coefficient: n-octanol/wa	ater: Not determined.	
· Viscosity: · dynamic: · kinematic:	Not determined. Not determined.	
· Solvent content:		
· Solids content: 9.2 Other information	21,6 % No further relevant information available.	

### SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability
  - · Conditions to be avoided: No decomposition if used and stored 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: None
  - · Additional information: -

### **SECTION 11: Toxicological information**

- · 11.1 Information on toxicological effects
  - · Acute toxicity Based on available data, the classification criteria are not met.

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· LD/LC50 values that are relevant for classification:				
		con dioxide, chemically prepared		
Oral	LD50	> 5000 mg/kg (rat)		
Dermal	LD50	> 5000 mg/kg (rabbit)		
16919-27-0 dipotassium hexafluorotitanate				
Oral	LD50	324 mg/kg (rat)		

- · Primary irritant effect:
  - Skin corrosion/irritation Based on available data, the classification criteria are not met.
  - Serious eye damage/irritation
  - Causes serious eye irritation.
- · Respiratory or skin sensitisation Guinea-Pig Maximisation Test (OECD 406): negative

Additional toxicological information:

The product contains no relevant dust particles (particel size > 100 micrometer) because the surface of the kieselguhr is coated with paraffin wax.

- CMR effects (carcinogenity, 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.
- 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

Small quantities can be polymerized with the matching system component(s) and the cured solid material can be disposed of with the regular garbage. Disposal must be made according to official regulations.

Uncleaned packagings:

Recommendation: Disposal must be made according to official regulations.

### SECTION 14: Transport information

· 14.1 UN-Number

ADR, ADN, IMDG, IATA

Void

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## Trade name: Alginoplast Cream Fast, Alginoplast Cream Normal

(Contd. of page 5) · 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA Void · 14.3 Transport hazard class(es) · ADR, ADN, IMDG, IATA · Class Void · 14.4 Packing group ADR, IMĎĞ, IAŤA Void · 14.5 Environmental hazards: Marine pollutant: No Not applicable. · 14.6 Special precautions for user · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code Not applicable. · Transport/Additional information: · UN "Model Regulation": 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.
    - REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
- · 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

### SECTION 16: Other information

These data are based on our present knowledge. However, they 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.

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)

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
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3