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

Version number 4 Printing date 03.06.2017 Revision: 03.06.2017

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

- · 1.1 Product identifier
 - · Trade name: Alginoplast
- · 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)

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 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 dipotassium hexafluorotitanate. May produce an allergic reaction.

Safety data sheet available on request.

- · 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: 68855-54-9	Kieselguhr, soda ash flux-calcined	50-75%		
EINECS: 272-489-0	STOT RE 2, H373			
	dipotassium hexafluorotitanate	0-5%		
EINECS: 240-969-9	Eye Dam. 1, H318; Acute Tox. 4, H302; Skin Sens. 1, H317; 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.

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 Instantly wash with water and soap and rinse thoroughly.
 - · After eye contact Rinse opened eye for several minutes under running water.
 - · 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 No further relevant information available.
- 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 13 for information on disposal.

See Section 8 for information on personal protection equipment.

SECTION 7: Handling and storage

- 7.1 Precautions for safe handling Wear protective equipment. Keep unprotected persons away.
 Information about protection against explosions and fires: No special measures required.
- · 7.2 Conditions for safe storage, including any incompatibilities
 - Storage
 - · 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.

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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:
14807-96-6 Talc (Mg3H2(SiO3)4)
WEL Long-term value: 1 mg/m³
8002-74-2 Paraffin waxes and Hydrocarbon waxes
WEL Short-term value: 6 mg/m³ Long-term value: 2 mg/m³
1309-48-4 magnesium oxide
WEL Long-term value: 10* 4** 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

Keep away from foodstuffs, beverages and food.

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

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

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SECTION 9: Physical and cher	mour proportion	
9.1 Information on basic physical and General Information Appearance:	d chemical properties	
Form:	Solid.	
· Colour:	According to product specification	
· Smell: · Odour threshold:	Aromatic Not determined.	
· pH-value:	Not determined. Not applicable.	
•	пот арріісавіе.	
Change in condition Melting point/Melting range: Boiling point/Boiling range:	Not determined Not determined	
0.		
· Flash point:	Not applicable	
· Inflammability (solid, gaseous)	Not determined.	
· Ignition temperature:		
· Decomposition temperature:	Not determined.	
· Self-inflammability:	Product is not selfigniting.	
· Danger of explosion:	Product is not explosive.	
 Critical values for explosion: Lower: Upper: 	Not determined. Not determined.	
· Steam pressure:	Not applicable.	
· Density	Not determined	
 Settled apparent density Relative density Vapour density Evaporation rate 	250-500 kg/m3 Not determined. Not applicable. Not applicable.	
Solubility in / Miscibility with Water:	Insoluble	
· Partition coefficient (n-octanol/wa	ater): Not determined.	
· Viscosity:		
dynamic:	Not applicable.	
· kinematic: 9.2 Other information	Not applicable. 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

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- 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

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 that are relevant for classification:

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 Based on available data, the classification criteria are not met.
- Respiratory or skin sensitisation Guinea-Pig Maximisation Test (OECD 406): negative

· Additional toxicological information:

The product contains no relevant dust particles (particle 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.

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Uncleaned packagings:

• Recommendation: Disposal must be made according to official regulations.

14.1 UN-Number			
· ADR, ADN, IMDG, IATA	Void		
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, IMDG, IATA	Void		
14.5 Environmental hazards: · Marine pollutant:	No		
14.6 Special precautions for user	Not applicable.		
· 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

· 15.2 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.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H335 May cause respiratory irritation.

H373 May cause damage to organs through prolonged or repeated exposure.

· 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

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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 Skin Sens. 1: Skin sensitisation – Category 1 STOT SE 3: Specific target organ toxicity (single exposure) – Category 3 STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2 * * Data compared to the previous version altered.

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