

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

071614494

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

071613629 071613637 071613801 071613835 071613959 071613983 071613991 071614007 071614023 071614031  
071614197 071614361 071614403 071614411 071614429 071614486 071614502 071620400 071620418

**The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).**

071613843



# SAFETY DATA SHEET

Revision Date 20/08/2013

## SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1 Product identifier

Product Name **Image Alginate**  
Synonyms Alginate impression materials

### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Dental impression material  
Uses advised against No information available

### 1.3 Details of the supplier of the safety data sheet

**Dux Dental B.V.**  
Zonnebaan 14  
3542 EC Utrecht  
The Netherlands  
Tel: +31 (0)30-24 10 924  
E-mail: info@dux-dental.com

### 1.4 Emergency telephone number

National Poisons Information Service (London Centre)  
+44 20 7771 5307

## SECTION 2: HAZARDS IDENTIFICATION

### 2.1 Classification of the substance or mixture

Classification according to EU Directives 67/548/EEC or 1999/45/EC  
Xi; R43 - Xn; R48/20 - R52/53

### 2.2 Label elements

This product is a medical device which is regulated under Directive 2007/47/EC (the Medical Device Directive) and complies with ISO 1563:1990. As such it does not present a significant risk to the user or patient when used in accordance with manufacturer's instructions. A Safety Data Sheet is not required for medical devices according to Regulation No 1907/2006 (REACH, Article 2, point 6). This Safety Data Sheet is supplied as an additional service. The product is classified as dangerous according to Directive 1999/45/EC and its amendments.

### 2.3 Other hazards

This product contains respirable quartz as an impurity.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.2 Mixtures

Chemical Name	EC-No	CAS-No	Weight %	Classification (67/548/EEC)	Classification (1272/2008/EC)	REACH Registration Number
Diatomaceous earth, flux-calcined	272-489-0	68855-54-9	>70	Xn; R48/20	STOT RE 2 H373	no data available
Dipotassium hexafluorotitanate	240-969-9	16919-27-0	1-2.5	Xn; R22-37/38-41-43	Acute Tox. 4 H302 Skin Irrit. 2 H315 Skin Sens. 1 H317 Eye Dam. 1 H318 STOT SE 3 H335	no data available
Tetrasodium pyrophosphate	231-767-1	7722-88-5	<1	Xi; R37-41	Eye Dam. 1 H318 STOT SE 3 H335	no data available
Magnesium oxide	215-171-9	1309-48-4	<1	-	-	no data available
Zinc oxide	215-222-5	1314-13-2	<0.25	N; R50/53	Aquatic Acute 1 H400 Aquatic Chronic 1 H410	no data available

For the full text of the R-phrases mentioned in this Section, see Section 16.  
For the full text of the H-Statements mentioned in this Section, see Section 16.

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

<b>General advice</b>	No hazards which require special first aid measures.
<b>Eye contact</b>	Rinse thoroughly with plenty of water, also under the eyelids. If symptoms persist, call a physician.
<b>Skin contact</b>	Wash skin with soap and water. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Get medical attention immediately if symptoms occur.
<b>Inhalation</b>	Move to fresh air. Get medical attention immediately if symptoms occur.
<b>Protection of first-aiders</b>	Use personal protective equipment. Avoid contact with skin, eyes and clothing.

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

<b>Main symptoms</b>	May cause sensitisation by skin contact. Causes damage to organs through prolonged or repeated exposure if inhaled.
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### 4.3 Indication of any immediate medical attention and special treatment needed

<b>Notes to physician</b>	Treat symptomatically.
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## SECTION 5: FIREFIGHTING MEASURES

### 5.1 Extinguishing media

**Suitable extinguishing media**            The product itself does not burn. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**Extinguishing media which must not be used for safety reasons**    None known.

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

**Special hazard**                                None in particular.

### 5.3 Advice for firefighters

**Special protective equipment for fire-fighters**    Wear self-contained breathing apparatus and protective suit.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

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

No special precautions.

### 6.2 Environmental precautions

Should not be released into the environment.

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

Sweep up and shovel into suitable containers for disposal.

### 6.4 Reference to other sections

See sections 8 and 13.

## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practice. Avoid dust formation. Avoid contact with skin, eyes and clothing.

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

Store in original container. Keep container tightly closed in a dry and well-ventilated place. Keep away from direct sunlight.

### 7.3 Specific end use(s)

**Exposure Scenario**                            Not available.

**Other information**                            Not available.

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

Chemical Name	European Union	The United Kingdom	France	Spain	Germany
Diatomaceous earth, flux-calcined					MAK: 0.3 mg/m <sup>3</sup> TWA: 0.3 mg/m <sup>3</sup>
Dipotassium hexafluorotitanate					TWA: 1 mg/m <sup>3</sup>
Tetrasodium pyrophosphate		TWA: 5 mg/m <sup>3</sup>	VME: 5 mg/m <sup>3</sup>	VLA-ED: 5 mg/m <sup>3</sup>	
Magnesium oxide		TWA: 10 mg/m <sup>3</sup> as Mg (Inhalable) TWA: 4 mg/m <sup>3</sup> as Mg (respirable)	VME: 10 mg/m <sup>3</sup> (fume)	VLA-ED: 10 mg/m <sup>3</sup>	
Zinc oxide			VME: 5 mg/m <sup>3</sup> (fume)	VLA-ED: 5 mg/m <sup>3</sup> VLA-EC: 10 mg/m <sup>3</sup>	

Chemical Name	Italy	Portugal	Netherlands	Denmark	Poland
Diatomaceous earth, flux-calcined					NDS: 2.0 mg/m <sup>3</sup> NDS: 1.0 mg/m <sup>3</sup>
Dipotassium hexafluorotitanate		TWA: 2.5 mg/m <sup>3</sup>	STEL: 2 mg/m <sup>3</sup>	TWA: 2.5 mg/m <sup>3</sup>	NDSch: 3 mg/m <sup>3</sup> NDS: 1 mg/m <sup>3</sup>
Tetrasodium pyrophosphate				TWA: 5 mg/m <sup>3</sup>	
Magnesium oxide		VLE-MP: 10 mg/m <sup>3</sup> (inhalable)		GV: 6 mg/m <sup>3</sup> as Mg	NDS: 5 mg/m <sup>3</sup> (fume) NDS: 10 mg/m <sup>3</sup> (dust)
Zinc oxide				GV: 4 mg/m <sup>3</sup>	

Chemical Name	Belgium	Sweden	Hungary	Finland	Czech Republic
Dipotassium hexafluorotitanate			STEL: 10 mg/m <sup>3</sup> TWA: 2.5 mg/m <sup>3</sup> *S		
Tetrasodium pyrophosphate	TWA: 5 mg/m <sup>3</sup>				
Magnesium oxide	TWA: 10 mg/m <sup>3</sup>		TWA: 6 mg/m <sup>3</sup> STEL: 24 mg/m <sup>3</sup>		Ceiling: 10 mg/m <sup>3</sup> TWA: 5 mg/m <sup>3</sup>
Zinc oxide	TWA: 5 mg/m <sup>3</sup> (inh) STEL: 10 mg/m <sup>3</sup> (inh)	NGV: 5 mg/m <sup>3</sup>	STEL: 20 mg/m <sup>3</sup> TWA: 5 mg/m <sup>3</sup>	TWA: 2 mg/m <sup>3</sup> STEL: 10 mg/m <sup>3</sup>	Ceiling: 5 mg/m <sup>3</sup> TWA: 2 mg/m <sup>3</sup>

#### Legend:

\* Skin designation

**Derived No Effect Level (DNEL)** No information available.

**Predicted No Effect Concentration (PNEC)** No information available.

### 8.2 Exposure controls

**Appropriate engineering controls** Ensure adequate ventilation, especially in confined areas.

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

<b>Eye protection</b>	No special protective equipment required.
<b>Hand protection</b>	Protective gloves.
<b>Skin and body protection</b>	Long sleeved clothing.
<b>Respiratory protection</b>	In case of insufficient ventilation wear suitable respiratory equipment.

**Hygiene measures** Handle in accordance with good industrial hygiene and safety practice.

**Environmental Exposure Controls** The product should not be allowed to enter drains, water courses or the soil.

<b>SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES</b>
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**9.1 Information on basic physical and chemical properties**

<b>Physical state @20°C</b>	solid
<b>Appearance</b>	Powder
<b>Colour</b>	various
<b>Odour</b>	pleasant
<b>pH</b>	No information available
<b>Melting/freezing point</b>	No information available
<b>Boiling point/boiling range</b>	No information available
<b>Flash point</b>	No information available
<b>Evaporation rate</b>	No information available
<b>Flammability (solid, gas)</b>	No information available
<b>Flammability Limits in Air</b>	No information available
<b>Vapour pressure</b>	No information available
<b>Vapour density</b>	No information available
<b>Relative density</b>	No information available
<b>Solubility</b>	
<b>Water solubility</b>	Formation of gel
<b>Partition coefficient (n-octanol/water)</b>	No information available
<b>Autoignition Temperature</b>	Not applicable
<b>Decomposition temperature</b>	No information available
<b>Viscosity, dynamic</b>	No information available
<b>Explosive properties</b>	No information available
<b>Oxidising Properties</b>	No information available

**9.2 Other information**

<b>Density</b>	various
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**SECTION 10: STABILITY AND REACTIVITY**

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**10.1 Reactivity**

No information available.

**10.2 Chemical stability**

Stable under normal conditions.

**10.3 Possibility of hazardous reactions**

Hazardous polymerisation does not occur.

**10.4 Conditions to avoid**

None known.

**10.5 Incompatible materials**

None in particular.

**10.6 Hazardous decomposition products**

None under normal use.

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## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

#### Acute toxicity

Ingestion	No known effect.
Skin contact	No known effect.
Inhalation	No known effect.

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Dipotassium hexafluorotitanate	169 mg/kg ( Rat )		
Tetrasodium pyrophosphate	2000 mg/kg ( Rat )		
Zinc oxide	5000 mg/kg ( Rat )		

<b>Skin corrosion/irritation</b>	No known effect.
<b>Serious eye damage/irritation</b>	No known effect. Dust contact with the eyes can lead to mechanical irritation.
<b>Respiratory or skin sensitisation</b>	May cause sensitisation by skin contact.
<b>Germ cell mutagenicity</b>	Not known to cause heritable genetic damage.
<b>Carcinogenicity</b>	Contains no ingredient listed as a carcinogen.
<b>Reproductive toxicity</b>	Not known to cause birth defects or have a deleterious effect on a developing fetus. Not known to adversely affect reproductive functions and organs.
<b>STOT-single exposure</b>	No known effect.
<b>STOT-repeated exposure</b>	May cause damage to organs through prolonged or repeated exposure. Route of Exposure: Inhalation.
<b>Aspiration hazard</b>	No known effect.



## SECTION 12: ECOLOGICAL INFORMATION

### 12.1 Toxicity

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Chemical Name	Toxicity to algae	Toxicity to fish	Toxicity to microorganisms	Toxicity to daphnia and other aquatic invertebrates.
Dipotassium hexafluorotitanate	EC50: 95 mg/L Desmodesmus subspicatus 96 h			
Zinc oxide		LC50: 1.1 mg/L Oncorhynchus mykiss 96 h		EC50: >1000 mg/L Daphnia magna 48h

### 12.2 Persistence and degradability

No information available.

### 12.3 Bioaccumulative potential

No information available.

### 12.4 Mobility in soil

No information available.

### 12.5 Results of PBT and vPvB assessment

No information available.

### 12.6 Other adverse effects

No information available.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

**Waste from residues / unused products**

Dispose of as hazardous waste in compliance with local and national regulations.

**Contaminated packaging**

Empty containers should be taken to an approved waste handling site for recycling or disposal.

**SECTION 14: TRANSPORT INFORMATION**

According to. ADR, RID, ADN, IMDG, ICAO.

**14.1 UN number**

Not regulated.

**14.2 UN proper shipping name**

Not regulated.

**14.3 Transport hazard class(es)**

Not regulated.

**14.4 Packing group**

Not regulated.

**14.5 Environmental hazards**

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

**14.6 Special precautions for user**

Not applicable.

**14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable.

**SECTION 15: REGULATORY INFORMATION****15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture****Restrictions on use**

None.

**Other regulations**

This product is a medical device which is regulated under Directive 2007/47/EC (the Medical Device Directive). As such it does not present a significant risk to the user or patient when used in accordance with manufacturer's instructions. A Safety Data Sheet is not required for medical devices according to Regulation No 1907/2006 (REACH, Article 2, point 6). This Safety Data Sheet is supplied as an additional service.

**15.2 Chemical safety assessment**

Not required.

**SECTION 16: OTHER INFORMATION****Full text of R-phrases referred to under sections 2 and 3**

R22 - Harmful if swallowed  
R37 - Irritating to respiratory system  
R37/38 - Irritating to respiratory system and skin  
R41 - Risk of serious damage to eyes  
R43 - May cause sensitisation by skin contact  
R48/20 - Harmful: danger of serious damage to health by prolonged exposure through inhalation  
R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment  
R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment

**Full text of H-Statements referred to under sections 2 and 3**

H302 - Harmful if swallowed  
H315 - Causes skin irritation  
H317 - May cause an allergic skin reaction  
H318 - Causes serious eye damage  
H335 - May cause respiratory irritation  
H373 - May cause damage to lung through prolonged or repeated exposure by inhalation  
H400 - Very toxic to aquatic life  
H410 - Very toxic to aquatic life with long lasting effects

**Revision Note**

Format updated in compliance with European REACH and CLP regulations.

**This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006**

**Disclaimer**

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text