

SAFETY DATA SHEETS

This SDS packet was issued with item:

071614007

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 071614023 071614031 071614197
071614361 071614403 071614411 071614429 071614486 071614494 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

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

4.2 Most important symptoms and effects, both acute and delayed

| | |
|----------------------|---|
| Main symptoms | May cause sensitisation by skin contact. Causes damage to organs through prolonged or repeated exposure if inhaled. |
|----------------------|---|

4.3 Indication of any immediate medical attention and special treatment needed

| | |
|---------------------------|------------------------|
| Notes to physician | Treat symptomatically. |
|---------------------------|------------------------|

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 ³ TWA: 0.3 mg/m ³ |
| Dipotassium hexafluorotitanate | | | | | TWA: 1 mg/m ³ |
| Tetrasodium pyrophosphate | | TWA: 5 mg/m ³ | VME: 5 mg/m ³ | VLA-ED: 5 mg/m ³ | |
| Magnesium oxide | | TWA: 10 mg/m ³ as Mg (Inhalable) TWA: 4 mg/m ³ as Mg (respirable) | VME: 10 mg/m ³ (fume) | VLA-ED: 10 mg/m ³ | |
| Zinc oxide | | | VME: 5 mg/m ³ (fume) | VLA-ED: 5 mg/m ³ VLA-EC: 10 mg/m ³ | |

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

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

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

| | |
|---------------------------------|--|
| Eye protection | No special protective equipment required. |
| Hand protection | Protective gloves. |
| Skin and body protection | Long sleeved clothing. |
| Respiratory protection | 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.

| |
|--|
| SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES |
|--|

9.1 Information on basic physical and chemical properties

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

9.2 Other information

| | |
|----------------|---------|
| Density | various |
|----------------|---------|

SECTION 10: STABILITY AND REACTIVITY

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) | | |

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