

Safety Data Sheet

According to 1907/2006/EC, Article 31

Printing date: 25.03.2010

Revision: 25.03.2010

1 Identification of the substance/preparation and of the company/undertaking

· Product details**· Trade name:** Image Alginate**· Synonyms:** Alginate Impression Materials**· Application of the substance/the preparation:** Dental impression material**· Manufacturer/Supplier:**

Dux Dental B.V.

Zonnebaan 14

3542 EC Utrecht

The Netherlands

tel: +31 (0)30-24 10 924

· Further information obtainable from: info@dux-dental.com**· Information in case of emergency:** National Poisons Information Service (NPIS): 0870 600 6266 (UK only)

2 Hazards identification

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.

· Hazard description:

Xn Harmful

· Information concerning particular hazards for human and environment:

Classification:

R43 May cause sensitisation by skin contact.

R48/20 Harmful: danger of serious damage to health by prolonged exposure through inhalation.

R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

· Classification system:

The classification is according to the latest editions of the EU-lists, and extended by company and literature.

· Additional information:

The above classification is applicable for the product as supplied in its powder form.

3 Composition/information on ingredients

· Chemical characterization**· Description:** Mixture of substances listed below with nonhazardous additions.**· Dangerous components:**

CAS: 68855-54-9 EINECS: 272-489-0	Kieselguhr, soda ash flux-calcined	Xn; R48/20	>70%
CAS: 16919-27-0 EINECS: 240-969-9	Dipotassium hexafluorotitanate	Xn; R22- 37/38-41-43	1-2.5%
CAS: 7722-88-5 EINECS: 231-767-1	Tetrasodium pyrophosphate	Xi; R37-41	<1%
CAS: 1309-48-4 EINECS: 215-717-9	Magnesium oxide		<1%



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(Contd. of page 1)

CAS: 1314-13-2

EINECS: 215-222-5

Zinc oxide

N; R50/53

<0.25%

4 First aid measures

- **General information:** No special measures required.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Immediately rinse with water.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** No special measure necessary. Consult doctor in case of complaints.

5 Fire-fighting measures

- **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Person-related safety precautions:** Not required.
- **Measures for environmental protection:** Do not allow product to reach sewage or any water course.
- **Measures for cleaning/collecting:** Wipe up with wet cloth. Dispose contaminated material as waste according to item 13.

7 Handling and storage

- **Handling:**
- **Information for safe handling:** As part of good industrial, personal hygiene, and safety practice avoid all unnecessary exposure to the substance and ensure prompt removal from skin, eyes and clothing. Prevent formation of dust.
- **Information about fire - and explosion protection:** No special measures required.
- **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:** Keep container tightly sealed.

8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Ingredients with limit values that require monitoring at the workplace:**
 - Tetrasodium pyrophosphate**
WEL Long-term value (TWA): 5 mg/m³ 8 hours
 - Magnesium oxide (as Mg)**
WEL Long-term value (TWA): 10 mg/m³ 8 hours inhalable dust
WEL Long-term value (TWA): 4 mg/m³ 8 hours fume and respirable dust
 - Silica, respirable crystalline**
WEL Long-term value (TWA): 0.1 mg/m³ 8 hours



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(Contd. of page 2)

- **Additional information:** The lists valid during the making were used as basis. 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.
- **Personal protective equipment:**
- **Respiratory protection:** Use suitable respiratory protective device in case of dust formation in excess of exposure limits.
- **Protection of hands:** Optional.
- **Eye protection:** Optional.

9 Physical and chemical properties

· General Information

Form:	Solid (powder)
Colour:	Varies with product.
Odour:	Pleasant

· Change in condition

Melting point:	Not available.
Boiling point:	Not available.

· **Flash point:** Not available.

· **Self ignition:** Product is not selfigniting.

· **Denstiy:** Varies with product.

· **Solubility in/miscibility with Water:**

Gel former.

10 Stability and reactivity

- **Thermal decomposition/conditions to be avoided:** No decomposition if used according to specifications.
- **Dangerous reactions:** No dangerous reactions known.
- **Dangerous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** May cause sensitisation by skin contact.
- **Additional toxicological information:**

This product contains a certain quantity of crystalline silica (quartz and cristobalite). Long term inhalation of respirable crystalline silica may lead to silicosis if the limit values are exceeded. Both of these substances have been classified as suspected carcinogens by IARC.

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(Contd. of page 3)

12 Ecological information

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

13 Disposal considerations

- **Product:**
- **Recommendation**
Disposal must be made according to official regulations. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- **Land transport ADR/RID (cross-border):**
- **ADR/RID class:** Not applicable
- **Maritime transport IMDG:**
- **IMDG class:** Not applicable
- **Air transport ICAO-TI en IATA-DGR:**
- **ICAO/IATA-class:** Not applicable

15 Regulatory information

- **Labelling according to EU guidelines:**
Observe the general safety regulations when handling chemicals.
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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 R-phrases**
22 Harmful if swallowed
37 Irritating to respiratory system.
37/38 Irritating to respiratory system and skin.
41 Risk of serious damage to eyes.
43 May cause sensitization in contact with skin.
48/20 Harmful: danger of serious damage to health by prolonged exposure through inhalation.
50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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