Revision: 03.07.2013

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

Printing date 03.07.2013

Version number 3

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

· 1.1 Product identifier

· Trade name: Jeltrate

Alginate Impression Material

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

No further relevant information available.

· Application of the substance / the preparation Dental impression material

· 1.3 Details of the supplier of the safety data sheet

· Manufacturer/Supplier:

DENTSPLY DeTrey GmbH

De-Trey-Str. 1

De-17ey-Sir. 1 D-78467 Konstanz

GERMANY

Tel.: +49-(0)7531-583-0

Fax: +49-(0)7531-583-104

email: KonstanzDEU.info-sdb@dentsply.com

· Further information obtainable from:

- Departement Analytical Research / Research & Development for technical information
- Departement Marketing & Sales for distribution of the safety data sheets
- · 1.4 Emergency telephone number: +49-(0)7531-583-0 8:00 17:00 (GMT + 1:00)

2 Hazards identification

- · 2.1 Classification of the substance or mixture
- · Classification according to Directive 67/548/EEC or Directive 1999/45/EC

Xn; Harmful

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

· Information concerning particular hazards for human and environment:

The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

Classification system:

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

- · 2.2 Label elements
- · Labelling according to EU guidelines:

The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials

· Code letter and hazard designation of product:



Xn Harmful

· Hazard-determining components of labelling:

Kieselguhr, soda ash flux-calcined cristobalite

· Risk phrases:

48/20 Harmful: danger of serious damage to health by prolonged exposure through inhalation.

- · Safety phrases:
- 22 Do not breathe dust.
- 25 Avoid contact with eyes.

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- 36 Wear suitable protective clothing.
- 38 In case of insufficient ventilation, wear suitable respiratory equipment.
- 60 This material and its container must be disposed of as hazardous waste.
- · 2.3 Other hazards
- · Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.

3 Composition/information on ingredients

- · 3.2 Chemical characterization: Mixtures
- · 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 STOT RE 2, H373	25-50%
CAS: 14464-46-1 EINECS: 238-455-4	cristobalite Xn R48/20 STOT RE 2, H373	10-25%
CAS: 1309-48-4 EINECS: 215-171-9 Index number: 025-199-09-0	magnesium oxide substance with a Community workplace exposure limit	2.5-10%
CAS: 7722-88-5 EINECS: 231-767-1	tetrasodium pyrophosphate Xn R22; Xi R41 Eye Dam. 1, H318; Acute Tox. 4, H302	≤ 2.5%

[·] Additional information For the wording of the listed risk phrases refer to section 16.

4 First aid measures

- · 4.1 Description of first aid measures
- · After inhalation Supply fresh air; consult doctor in case of complaints.
- · After skin contact Immediately wash with water and soap and rinse thoroughly.
- · After eye contact Rinse opened eye for several minutes under running water.
- · After swallowing If symptoms persist 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.

5 Firefighting measures

- · 5.1 Extinguishing media
- · Suitable extinguishing agents CO2, powder or water spray. Fight larger fires with water spray.
- · 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- · 5.3 Advice for firefighters
- · Protective equipment: Self-contained respiratory protective device.

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6 Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures

Avoid formation of dust.

Ensure adequate ventilation

Wear protective clothing.

- · 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · 6.3 Methods and material for containment and cleaning up:

Dispose contaminated material as waste according to item 13.

· 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 disposal information.

7 Handling and storage

· 7.1 Precautions for safe handling

Use appropriate industrial vacuum cleaners or central vacuum systems for dust removal.

Prevent formation of dust.

Observe normal care for working with chemicals.

- · Handling Product is intended for dental use only.
- · Information about fire and explosion protection: No special measures required.
- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage
- · Requirements to be met by storerooms and receptacles: Store only in the original receptacle.
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions: Protect from humidity and water.
- · 7.3 Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

- · Additional information about design of technical facilities: No further data; see item 7.
- · 8.1 Control parameters.

· Ingredients with limit values that require monitoring at the workplace:

1309-48-4 magnesium oxide

WEL Long-term value: 10* 4** mg/m3

(as Mg) *inhalable dust **fume and respirable dust

7722-88-5 tetrasodium pyrophosphate

WEL | Long-term value: 5 mg/m³

- · Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Personal protective equipment
- · General protective and hygienic measures

Vacuum clean contaminated clothing. Do not blow or brush off contamination.

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

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· Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

Not necessary if room is well-ventilated.

· Protection of hands:

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

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· 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.

· Eye protection: Safety glasses

· Body protection: Protective work clothing.

9 Physical and chemical properties

· 9.1 Information on basic physical a	and chemical properties
· General Information	
Appearance: Form:	Powder
Colour:	Different according to colouring
· Odour:	Product specific
· Odour threshold:	Not determined.
· pH-value:	Not applicable.
· Change in condition	
Melting point/Melting range:	undetermined
Boiling point/Boiling range:	undetermined
· Flash point:	Not applicable
· Flammability (solid, gaseous)	Not determined.
· Ignition temperature:	
Decomposition temperature:	Not determined.
· Self-igniting:	Product is not selfigniting.
· Danger of explosion:	Product does not present an explosion hazard.
· Explosion limits:	·
Lower:	Not determined.
Upper:	Not determined.
· Vapour pressure:	Not applicable.
· Density at 20 °C:	0.3 g/cm³
· Relative density	Not determined.
· Vapour density	Not applicable.

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Evaporation rate	Not applicable.	
· Solubility in / Miscibility with Water:	Partly soluble	
· Partition coefficient (n-octanol/	water): Not determined.	
Viscosity: dynamic: kinematic:	Not applicable. Not applicable.	
· Solvent content: Organic solvents:	0.0 %	
Solids content: · 9.2 Other information	100.0 % No further relevant information available.	

10 Stability and reactivity

- · 10.1 Reactivity
- · 10.2 Chemical stability
- · Thermal decomposition / conditions to be avoided: No decomposition if used 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: No dangerous decomposition products known

11 Toxicological information

- · 11.1 Information on toxicological effects
- · Acute toxicity:
- · Primary irritant effect:
- · on the skin: may cause skin irritation
- on the eye: Irritating effect.
- · Sensitization: No sensitizing effects known.
- · Additional toxicological information:

The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

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.
- · Additional ecological information:
- · General notes:

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

- · 12.5 Results of PBT and vPvB assessment
- · PBT: Not applicable.

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- · vPvB: Not applicable.
- · 12.6 Other adverse effects No further relevant information available.

13 Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation



Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· European waste catalogue

18 01 06* chemicals consisting of or containing dangerous substances

- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.
- · Recommended cleansing agents: Water, if necessary together with cleansing agents.

14 Transport information

· 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 Anne MARPOL73/78 and the IBC Code	ex II of Not applicable.	

15 Regulatory information

· 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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.

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are (Contd. on page 7)

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released, for example due to accidents during transport or storage by the dealer.

For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.

Relevant phrases

H302 Harmful if swallowed.

H318 Causes serious eye damage.

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

R22 Harmful if swallowed.

R41 Risk of serious damage to eyes.

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

· Department issuing MSDS: Analytical Research

· Contact: HotLine for urgent technical support: +49-7531-583-333

· * Data compared to the previous version altered.

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