

SAFETY DATA SHEETS

This SDS packet was issued with item:

071743459

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

071743905 071743954

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).

071742279 071742303 071742337 071743418 071743434 071743442 071743475 071743491 071743509 071743517
071743525 071743921 071744028 078292603 078292606 078293303 078293306 078293403 078293406

**DENTSPLY/International
DENTSPLY/Caulk
Safety Data Sheet**

508058

1. Identification

Product Name JELTRATE®	SDS Code Number 508058
Substance Identity JELTRATE® Alginate Impression Material	Date of Last Revision 09/11/12
Manufacturer: DENTSPLY Caulk	Address 38 West Clarke Avenue Milford DE 19963-1805 http://www.caulk.com http://www.dentsply.com
Grades or Minor Variant Identities Fast Set and Regular Set	Information Telephone Number (302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)
Product Use (for Canada) Dental Alginate Impression Material	Emergency Telephone Number (302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)

2. Hazard(s) Identification



Danger

**May cause cancer by inhalation
May causes damage to lungs through
prolonged or repeated exposure**



Warning

Causes skin irritation

Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Use personal protective equipment required.
If exposed or concerned: Get medical attention.
Store locked up.
Dispose of contents/container in accordance with local regulations
Wash hands thoroughly after handling.
Wear protective gloves.
If on skin: Wash with plenty of soap and water.
If skin irritation occurs: Get medical advice/attention.
Take off contaminated clothing and wash before reuse.

3. Composition/Information on Ingredients

Hazardous Components	C.A.S. Number	Exposure Limits	%
Silicon Dioxide -Crystalline - Cristobalite	14464-46-1	0.025 mg/M ³	< than 26
Silicon Dioxide - Crystalline -Quartz	14808-60-7	0.025 mg/M ³	< than 3
Silicon Dioxide – Amorphous - Diatomaceous Earth	68855-54-9	0.1 mg/M ³	< than 35
Calcium Sulfate	10101-41-4	10 mg/M ³	< than 20
Magnesium Oxide	1309-48-4	10 mg/M ³	< than 7
Tetrasodium Pyrophosphate	7722-88-5	5 mg/M ³	< than 3

Colorant Information: Fast Set Product contains D & C Red # 30 Aluminum Lake as colorant.

Regular Set Product contains synthetic Yellow Iron Oxide as colorant.

4. First Aid Measures

Routes of Exposure	First Aid Instructions	Immediate Medical Attention	Delayed Effects
Eye	Rinse opened eye for several minutes under running water. If symptoms persist consult physician	Not Applicable	Not Applicable
Skin	Immediately wash with soap and water and rinse	Not Applicable	Not Applicable

	thoroughly		
Inhalation	Supply fresh air, consult physician if symptoms persist	Not Applicable	Irritation and soreness in throat and nose. In extreme exposures some congestion may occur. Inhalation of crystalline silica has been classified by IARC as carcinogenic for humans (Group 1). Inhalation of crystalline silica is also a known cause of silicosis, a non-cancerous lung disease caused by excessive exposure to crystalline silica. Respirable dust from this product may contain up to 26 % free crystalline silica (Cristobalite) and up to 3% crystalline silica (Quartz). As such it represents a risk to the respiratory system. Long term, unprotected exposure to dust levels in excess of the TLV or PEL may cause lung disease (silicosis).
Ingestion	If symptoms persist consult physician	Not Applicable	Low order of toxicity is expected when material is ingested.
Other	Not Applicable	Not Applicable	Not Applicable
Note to Physicians (Treating, Testing and Monitoring): Treat symptomatically.			

5. Fire and Explosion Data

Flashpoint Method: Not Applicable	Flammable (Explosive) Limits in Air LEL: Not Applicable UEL: Not Applicable	Autoignition Temperature: Not Applicable	Other: Not Applicable
Flame Propagation or Burning Rate (for Solids): Not Applicable	Properties Contributing to Fire Intensity: Not Applicable	Flammability Classification: Not Applicable	
Extinguishing Media: Not Applicable		Extinguishing Media to Avoid: Water with full jet.	
Protection and Procedures for Firefighters: Firefighters should wear self-contained respiratory protective devices.			
Unusual Fire and Explosion Hazards: In common with most inorganic / organic materials, this product should be treated as a combustible dust in the finely divided and suspended state. No dangerous decomposition products known. - Product does not present an explosion hazard.			

6. Accidental Release Measures

Containment Techniques: Material is a dry fluffy powder, which is colored pale yellow or pink. Store only in the original package. Keep package tightly sealed to minimize dust generation and accumulation. The avoidance of any air contaminant is always a recommended practice. Adherence to work place ventilation standards is an assurance of general personnel health and comfort		
Spill/Leak Clean-up Procedures and Equipment: Wear protective clothing and scoop up bulk material and place in a labeled plastic or metal container. Avoid gross skin contact to minimize the possibility of drying out the skin. Ensure adequate ventilation, by either natural or mechanical means to keep dust level below PEL.		
Evacuation Procedures: Not Applicable	Special Instructions: Not Applicable	Reporting Requirements: Not Applicable

7. Handling and Storage

Handling Practices and Warnings: Product is intended for dental use only. Handling of this product should be by trained dental healthcare professionals only. Observe normal care for working with chemicals.
Storage Practices and Warnings: Store only in the original package. Keep package tightly sealed. Store in a dry area. Protect from exposure to direct light. Store in a cool dry area. Store away from food and beverages. Minimize dust generation and accumulation. Avoid breathing dust and contact with eyes. Return cap to canisters immediately. Close pouches immediately after use. Continue to follow all MSDS/label warnings when handling empty containers. Observe normal warehouse handling procedures. The avoidance of any air contaminant is always a recommended practice. Adherence to work place ventilation standards is an assurance of general personnel health and comfort.

8. Exposure Control / Personal Protection



Ventilation: Ensure adequate ventilation, by either natural or mechanical means to keep dust level below PEL.		Other Engineering Controls: Not Applicable
Routes of Entry	Personal Protective Equipment (PPE) for Normal Use	PPE for Emergencies
Eye/Face	Safety Glasses	Not Applicable
Skin	The glove material has to be impermeable and resistant to the product.	Not Applicable
Inhalation	Recommended NIOSH approved nuisance dust mask. <10X PEL, use 3M 9900; <100X PEL, use MSA Ultra-Twin with H filter; <200X PEL, use MSA 01-00-06 with type C supplied air unit (continuous flow mode); or equivalent. Use sufficient natural or mechanical ventilation to keep dust level below PEL.	Not Applicable
Body Protection	Protective work clothing such as lab coat.	Not Applicable
General Hygiene Considerations and Work Practices: Avoid dusting when in use. Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at end of work. Avoid contact with the eyes and skin. Do not eat, drink or smoke when using.		
Protective Measures During Repair and Maintenance of Contaminated Equipment: Not Applicable		
Other Protective Measures and Equipment: Not Applicable		

9. Physical and Chemical Characteristics

Appearance: Dry fluffy powder. May be colored pink or light yellow.	Odor: Spearmint odor.	
Normal Physical State: Dry fluffy powder.	Melting Point: Not Applicable	
Specific Gravity: 0.3 g/cm ³	Solubility in Water: Partially soluble	pH: Not Applicable
Vapor Pressure (mm Hg): Not Applicable	Vapor Density (AIR=1):	Evaporation Rate (Butyl Acetate =1): Not Applicable
Other: Not Applicable		

10. Stability and Reactivity Data

Incompatibility (Materials to Avoid): Hydrofluoric Acid.		
Hazardous Products Produced During Decomposition: No dangerous decomposition products known if used according to Directions for Use. (DFU).		
Hazardous Polymerization: <input type="checkbox"/> May Occur <input checked="" type="checkbox"/> May Not Occur	Conditions to Avoid: None known	
Stability? <input checked="" type="checkbox"/> Stable <input type="checkbox"/> Unstable	Conditions to Avoid: None known	

11.Toxicological Information

Toxicity Data, Epidemiology Studies, Carcinogenicity, Neurological Effects, Genetic Effects, Reproductive Effects, or Structure Activity Data: Inhalation of crystalline silica has been classified by IARC as carcinogenic for humans (Group1). Inhalation of crystalline silica is also a known cause of silicosis, a non-cancerous lung disease caused by excessive exposure to crystalline silica. Respirable dust from this product may contain up to 26 % free crystalline silica (Cristobalite). As such it represents a risk to the respiratory system. Long term, unprotected exposure to dust levels in excess of the TLV or PEL may cause lung disease (silicosis). The dry product may irritate the skin by drying it out.					
Emergency Overview: Inhalation of crystalline silica has been classified by IARC as carcinogenic for humans (Group 1). Inhalation of crystalline silica is also a known cause of silicosis, a non-cancerous lung disease caused by excessive exposure to crystalline silica. Respirable dust from this product may contain up to 26 % crystalline silica (Cristobalite) and up to 3% crystalline silica (Quartz). As such, it represents a risk to the respiratory system. Long term, unprotected exposure to dust levels in excess of the TLV or PEL may cause lung disease (silicosis).					
Routes of Exposure	Signs and Symptoms	Single, Repeated, or Lifetime Exposure	Severity (Mild, Moderate, Severe)	Acute and Chronic Health Effect(s)	Target Organ(s)
Eye	Material can cause irritation.	Single	Moderate	Irritation and possible corneal damage	Not Applicable
Skin	Material may be an irritant	Single & Repeated	Moderate	Irritation or possible allergic response.	Not Applicable
Inhalation	Transitory upper respiratory irritation or eye irritation.	Single & Repeated	Moderate	Irritation and soreness in throat and nose. In extreme exposures some congestion may occur. Inhalation of crystalline silica has been classified by IARC as carcinogenic for humans (Group1). Inhalation of crystalline silica is also a known cause of silicosis, a non-cancerous lung disease caused by excessive exposure to crystalline silica. Respirable dust from this product may contain up to 26 % free crystalline silica (Cristobalite) and up to 3 % crystalline silica (Quartz). As such it represents a risk to the respiratory system. Long term, unprotected exposure to dust levels in excess of the TLV or PEL may cause lung disease (silicosis).	Lung
Ingestion	Material is probably not harmful if swallowed	Not Applicable	Mild	Low order of toxicity is expected when material is ingested.	Not Applicable
Other	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Medical Conditions Aggravated by Exposure: Open sores and wounds of the skin.					
Carcinogenicity NTP?: Not listed IARC monographs?: Yes Group 1 OSHA regulated?: No, All components of this product are in compliance with the inventory listing Requirements of the U. S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory.					
Potential Environmental Effects Do not allow to enter sewers/ surface or ground water.					
NFPA Hazard Classification Ratings (Scale 0-4), Health = 3, Fire = 0, Reactivity = 0					

12.Ecological Information

Toxicity Data, Environmental Fate, Physical/Chemical Data, or other Data Supporting Environmental Hazard Statements: Water Hazard class1 (Self-assessment): slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water streams or sewage system.

13.Disposal Considerations

Regulations: Dispose of material as solid waste in a closed container. Dispose of in accordance with Federal, State and Local regulations. Vacuum clean dust with equipment fitted with a HEPA filter. Use dust suppression such as water if sweeping is necessary. Sweep up spilled material and place in closed containers for disposal.
Properties (Physical/Chemical) Affecting Disposal: Dispose of material as solid waste in a closed container.

14.Transport Information

Regulated for Shipping: No. Not Regulated	DOT Shipping Name: Not Regulated	Packing Group: Not Applicable
Do Changes in Quantities, packaging, or shipment method change product classification? No	DOT Hazard Class: Not Applicable	UN Number: Not Applicable

15.Regulatory Information

This product has been classified in accordance with the hazard criteria of the Globally Harmonized System of Classification and Labeling of Chemicals and the SDS contains all of the information required by the Canadian Controlled Products Regulations.
U.S. Federal Regulations: <u>CERCLA 103 Reportable Quantity</u> : This product is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations
<u>Section 313 Toxic Chemicals</u> : This product contains the following chemicals subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372): None
<u>Section 302 Extremely Hazardous Substances (TPQ)</u> : None
<u>EPA Toxic Substances Control Act (TSCA) Status</u> : All of the components of this product are listed on the TSCA inventory.
<u>U.S. State Regulations California Proposition 65</u> :
Warning: This product contains silica, crystalline (airborne particles of respirable size) which is known by the State of California to cause cancer.
<u>International Regulations: Canadian Environmental Protection Act</u> :
This product is a medical device and not subject to chemical notification requirements.
<u>European Community Labeling</u> : Not a dangerous preparation.
<u>European Inventory of New and Existing Chemicals Substances (EINECS)</u> :
This product is a medical device and not subject to chemical notification requirements.

16. Other Information

To the best of our knowledge this product does not contain gluten, wheat grains, flaxseed, natural rubber, or natural latex.

All components are synthetically produced; none are derived from animal products.

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific products 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 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.

Dentsply Jeltrate Alginate Impression Material

Dentsply Sirona Pty Ltd

Chemwatch: 4993-56

Version No: 5.1.1.1

Safety Data Sheet according to WHS and ADG requirements

Chemwatch Hazard Alert Code: 3

Issue Date: 27/06/2017

Print Date: 04/01/2018

S.GHS.AUS.EN

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

Product Identifier

Product name	Dentsply Jeltrate Alginate Impression Material
Synonyms	Not Available
Other means of identification	Not Available

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

Relevant identified uses	Dental alginate impression material.
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Details of the supplier of the safety data sheet

Registered company name	Dentsply Sirona Pty Ltd
Address	11-21 Gilby Road Mount Waverley VIC 3149 Australia
Telephone	1300 55 29 29
Fax	1300 55 31 31
Website	www.dentsply.com.au
Email	clientservices@dentsplysirona.com

Emergency telephone number

Association / Organisation	Not Available
Emergency telephone numbers	1300 55 29 29
Other emergency telephone numbers	Not Available

SECTION 2 HAZARDS IDENTIFICATION

Classification of the substance or mixture

HAZARDOUS CHEMICAL. NON-DANGEROUS GOODS. According to the WHS Regulations and the ADG Code.

CHEMWATCH HAZARD RATINGS

	Min	Max
Flammability	1	
Toxicity	2	
Body Contact	2	
Reactivity	1	
Chronic	3	

0 = Minimum
1 = Low
2 = Moderate
3 = High
4 = Extreme

Poisons Schedule	Not Applicable
Classification [1]	Eye Irritation Category 2A, Skin Sensitizer Category 1, Germ cell mutagenicity Category 2, Carcinogenicity Category 1A, Specific target organ toxicity - single exposure Category 3 (respiratory tract irritation), Specific target organ toxicity - repeated exposure Category 2
Legend:	1. Classified by Chemwatch; 2. Classification drawn from HSIS ; 3. Classification drawn from EC Directive 1272/2008 - Annex VI

Label elements

Hazard pictogram(s)	
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SIGNAL WORD	DANGER
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Hazard statement(s)

H319	Causes serious eye irritation.
H317	May cause an allergic skin reaction.
H341	Suspected of causing genetic defects.
H350	May cause cancer.
H335	May cause respiratory irritation.

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H373	May cause damage to organs through prolonged or repeated exposure.
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Precautionary statement(s) Prevention

P201	Obtain special instructions before use.
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P271	Use only outdoors or in a well-ventilated area.
P280	Wear protective gloves/protective clothing/eye protection/face protection.

Precautionary statement(s) Response

P308+P313	IF exposed or concerned: Get medical advice/attention.
P363	Wash contaminated clothing before reuse.
P302+P352	IF ON SKIN: Wash with plenty of soap and water.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Precautionary statement(s) Storage

P405	Store locked up.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.

Precautionary statement(s) Disposal

P501	Dispose of contents/container in accordance with local regulations.
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SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

Substances

See section below for composition of Mixtures

Mixtures

CAS No	%[weight]	Name
68855-54-9	<35	<u>diatomaceous earth, flux-calcined</u>
14464-46-1	<26	<u>cristobalite</u>
7778-18-9	<20	<u>calcium sulfate</u>
1309-48-4	<7	<u>magnesium oxide</u>
14808-60-7	<3	<u>silica crystalline - quartz</u>
7722-88-5	<3	<u>tetrasodium pyrophosphate</u>
		regular set product contains colourant:
Not Available	NotSpec.	<u>Yellow Iron Oxide</u>
		fast set product contains colourant:
1342-90-1	NotSpec.	<u>D&C Red No.30 Aluminium Lake</u>

SECTION 4 FIRST AID MEASURES

Description of first aid measures

Eye Contact	If this product comes in contact with the eyes: <ul style="list-style-type: none"> Wash out immediately with fresh running water. Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. Seek medical attention without delay; if pain persists or recurs seek medical attention. Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	If skin or hair contact occurs: <ul style="list-style-type: none"> Flush skin and hair with running water (and soap if available). Seek medical attention in event of irritation.
Inhalation	<ul style="list-style-type: none"> If fumes or combustion products are inhaled remove from contaminated area. Lay patient down. Keep warm and rested. Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures. Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary. Transport to hospital, or doctor, without delay.
Ingestion	<ul style="list-style-type: none"> Immediately give a glass of water. First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5 FIREFIGHTING MEASURES

Extinguishing media

Dentsply Jeltrate Alginate Impression Material

- There is no restriction on the type of extinguisher which may be used.
- Use extinguishing media suitable for surrounding area.

Special hazards arising from the substrate or mixture

Fire Incompatibility	‣ Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result
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Advice for firefighters

Fire Fighting	<ul style="list-style-type: none"> ‣ When silica dust is dispersed in air, firefighters should wear inhalation protection as hazardous substances from the fire may be adsorbed on the silica particles. ‣ When heated to extreme temperatures, (>1700 deg.C) amorphous silica can fuse. ‣ Alert Fire Brigade and tell them location and nature of hazard. ‣ Wear breathing apparatus plus protective gloves in the event of a fire. ‣ Prevent, by any means available, spillage from entering drains or water courses. ‣ Use fire fighting procedures suitable for surrounding area.
Fire/Explosion Hazard	<ul style="list-style-type: none"> ‣ Solid which exhibits difficult combustion or is difficult to ignite. ‣ Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. ‣ Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust (420 micron or less) may burn rapidly and fiercely if ignited; once initiated larger particles up to 1400 microns diameter will contribute to the propagation of an explosion. ‣ A dust explosion may release large quantities of gaseous products; this in turn creates a subsequent pressure rise of explosive force capable of damaging plant and buildings and injuring people. <p>Combustion products include:</p> <ul style="list-style-type: none"> ‣ carbon monoxide (CO) ‣ carbon dioxide (CO₂) ‣ sulfur oxides (SO_x) ‣ silicon dioxide (SiO₂) ‣ metal oxides ‣ other pyrolysis products typical of burning organic material. <p>May emit poisonous fumes. May emit corrosive fumes.</p>
HAZCHEM	Not Applicable

SECTION 6 ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

See section 8

Environmental precautions

See section 12

Methods and material for containment and cleaning up

Minor Spills	<ul style="list-style-type: none"> ‣ Clean up waste regularly and abnormal spills immediately. ‣ Avoid breathing dust and contact with skin and eyes. ‣ Wear protective clothing, gloves, safety glasses and dust respirator. ‣ Use dry clean up procedures and avoid generating dust.
Major Spills	<p>Moderate hazard.</p> <ul style="list-style-type: none"> ‣ CAUTION: Advise personnel in area. ‣ Alert Emergency Services and tell them location and nature of hazard. ‣ Control personal contact by wearing protective clothing.

Personal Protective Equipment advice is contained in Section 8 of the SDS.

SECTION 7 HANDLING AND STORAGE

Precautions for safe handling

Safe handling	<ul style="list-style-type: none"> ‣ Avoid all personal contact, including inhalation. ‣ Wear protective clothing when risk of exposure occurs. ‣ Use in a well-ventilated area. ‣ Prevent concentration in hollows and sumps. ‣ Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions) ‣ Minimise airborne dust and eliminate all ignition sources. Keep away from heat, hot surfaces, sparks, and flame. ‣ Establish good housekeeping practices. ‣ Remove dust accumulations on a regular basis by vacuuming or gentle sweeping to avoid creating dust clouds.
Other information	<ul style="list-style-type: none"> ‣ Store in original containers. ‣ Keep containers securely sealed. ‣ Store in a cool, dry area protected from environmental extremes. ‣ Store away from incompatible materials and foodstuff containers.

Conditions for safe storage, including any incompatibilities

Suitable container	<ul style="list-style-type: none"> ‣ Polyethylene or polypropylene container. ‣ Check all containers are clearly labelled and free from leaks.
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Storage incompatibility

Calcium sulfate:

- ▶ reacts violently with reducing agents, acrolein, alcohols, chlorine trifluoride, diazomethane, ethers, fluorine, hydrazine, hydrazinium perchlorate, hydrogen peroxide, finely divided aluminium or magnesium, peroxyfuroic acid, red phosphorus, sodium acetylide
- ▶ sensitises most organic azides which are unstable shock- and heat- sensitive explosives
- ▶ may form explosive materials with 1,3-di(5-tetrazolyl)triazene
- ▶ is incompatible with glycidol, isopropyl chlorocarbonate, nitrosyl perchlorate, sodium borohydride
- ▶ is hygroscopic; reacts with water to form gypsum and Plaster of Paris

Silicas:

- ▶ react with hydrofluoric acid to produce silicon tetrafluoride gas
- ▶ react with xenon hexafluoride to produce explosive xenon trioxide
- ▶ reacts exothermically with oxygen difluoride, and explosively with chlorine trifluoride (these halogenated materials are not commonplace industrial materials) and other fluorine-containing compounds
- ▶ may react with fluorine, chlorates
- ▶ are incompatible with strong oxidisers, manganese trioxide, chlorine trioxide, strong alkalis, metal oxides, concentrated orthophosphoric acid, vinyl acetate
- ▶ may react vigorously when heated with alkali carbonates.
- ▶ Avoid reaction with oxidising agents

SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

OCCUPATIONAL EXPOSURE LIMITS (OEL)

INGREDIENT DATA


Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Australia Exposure Standards	cristobalite	Cristobalite (respirable dust)	0.1 mg/m ³	Not Available	Not Available	Not Available
Australia Exposure Standards	cristobalite	Cristobalite (respirable dust)	0.1 mg/m ³	Not Available	Not Available	Not Available
Australia Exposure Standards	calcium sulfate	Calcium sulphate	10 mg/m ³	Not Available	Not Available	Not Available
Australia Exposure Standards	magnesium oxide	Magnesium oxide (fume)	10 mg/m ³	Not Available	Not Available	Not Available
Australia Exposure Standards	silica crystalline - quartz	Silica - Crystalline	Not Available	Not Available	Not Available	Not Available
Australia Exposure Standards	silica crystalline - quartz	Quartz (respirable dust)	0.1 mg/m ³	Not Available	Not Available	Not Available
Australia Exposure Standards	silica crystalline - quartz	Quartz (respirable dust)	0.1 mg/m ³	Not Available	Not Available	Not Available
Australia Exposure Standards	tetrasodium pyrophosphate	Tetrasodium pyrophosphate	5 mg/m ³	Not Available	Not Available	Not Available

EMERGENCY LIMITS

Ingredient	Material name	TEEL-1	TEEL-2	TEEL-3
cristobalite	Cristobalite	0.075 mg/m ³	33 mg/m ³	200 mg/m ³
calcium sulfate	Calcium(II) sulfate dihydrate (1:1:2)	30 mg/m ³	330 mg/m ³	2,000 mg/m ³
calcium sulfate	Calcium sulfate anhydrous; (Drierite; Gypsum; Plaster of Paris)	30 mg/m ³	330 mg/m ³	2,000 mg/m ³
magnesium oxide	Magnesium oxide	30 mg/m ³	120 mg/m ³	730 mg/m ³
silica crystalline - quartz	Silica, crystalline-quartz; (Silicon dioxide)	0.075 mg/m ³	33 mg/m ³	200 mg/m ³
tetrasodium pyrophosphate	Sodium pyrophosphate decahydrate	8.6 mg/m ³	96 mg/m ³	580 mg/m ³
tetrasodium pyrophosphate	Tetrasodium pyrophosphate	15 mg/m ³	130 mg/m ³	790 mg/m ³

Ingredient	Original IDLH	Revised IDLH
diatomaceous earth, flux-calcined	Not Available	Not Available
cristobalite	25 mg/m ³	Not Available
calcium sulfate	Not Available	Not Available
magnesium oxide	750 mg/m ³	Not Available
silica crystalline - quartz	Not Available	Not Available
tetrasodium pyrophosphate	Not Available	Not Available
Yellow Iron Oxide	Not Available	Not Available
D&C Red No.30 Aluminium Lake	Not Available	Not Available

Exposure controls

Appropriate engineering controls	<p>Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection.</p> <p>The basic types of engineering controls are:</p> <p>Process controls which involve changing the way a job activity or process is done to reduce the risk.</p> <p>Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment.</p>
Personal protection	
Eye and face protection	<ul style="list-style-type: none"> ▶ Safety glasses with side shields. ▶ Chemical goggles. ▶ Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task.

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Skin protection	See Hand protection below
Hands/feet protection	<p>The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical 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.</p> <p>The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice.</p> <p>Personal hygiene is a key element of effective hand care.</p> <p>Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.</p> <ul style="list-style-type: none"> ▶ polychloroprene. ▶ nitrile rubber. ▶ butyl rubber.
Body protection	See Other protection below
Other protection	<ul style="list-style-type: none"> ▶ Overalls. ▶ P.V.C. apron. ▶ Barrier cream.
Thermal hazards	Not Available

Respiratory protection

Particulate. (AS/NZS 1716 & 1715, EN 143:2000 & 149:001, ANSI Z88 or national equivalent)

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	P1 Air-line*	- -	PAPR-P1 -
up to 50 x ES	Air-line**	P2	PAPR-P2
up to 100 x ES	-	P3	-
		Air-line*	-
100+ x ES	-	Air-line**	PAPR-P3

* - Negative pressure demand ** - Continuous flow

A (All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO₂), G = Agricultural chemicals, K = Ammonia(NH₃), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

If inhalation risk above the TLV exists, wear approved dust respirator.

Use respirators with protection factors appropriate for the exposure level.

- ▶ Up to 5 X TLV, use valveless mask type; up to 10 X TLV, use 1/2 mask dust respirator
- ▶ Up to 50 X TLV, use full face dust respirator or demand type C air supplied respirator
- ▶ Up to 500 X TLV, use powered air-purifying dust respirator or a Type C pressure demand supplied-air respirator
- ▶ Over 500 X TLV wear full-face self-contained breathing apparatus with positive pressure mode or a combination respirator with a Type C positive pressure supplied-air full-face respirator and an auxiliary self-contained breathing apparatus operated in pressure demand or other positive pressure mode
- ▶ Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures.
- ▶ The decision to use respiratory protection should be based on professional judgment that takes into account toxicity information, exposure measurement data, and frequency and likelihood of the worker's exposure - ensure users are not subject to high thermal loads which may result in heat stress or distress due to personal protective equipment (powered, positive flow, full face apparatus may be an option).
- ▶ Published occupational exposure limits, where they exist, will assist in determining the adequacy of the selected respiratory protection. These may be government mandated or vendor recommended.
- ▶ Certified respirators will be useful for protecting workers from inhalation of particulates when properly selected and fit tested as part of a complete respiratory protection program.
- ▶ Use approved positive flow mask if significant quantities of dust becomes airborne.
- ▶ Try to avoid creating dust conditions.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance	Dry fluffy, may be coloured pale yellow or pink, powder with a spearmint odour; partly mixes with water.		
Physical state	Divided Solid	Relative density (Water = 1)	0.3
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Applicable
pH (as supplied)	Not Available	Decomposition temperature	Not Applicable
Melting point / freezing point (°C)	Not Applicable	Viscosity (cSt)	Not Available
Initial boiling point and boiling range (°C)	Not Applicable	Molecular weight (g/mol)	Not Applicable
Flash point (°C)	Not Applicable	Taste	Not Available
Evaporation rate	Not Applicable	Explosive properties	Not Available
Flammability	Not Applicable	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not Applicable	Surface Tension (dyn/cm or mN/m)	Not Applicable
Lower Explosive Limit (%)	Not Applicable	Volatile Component (%vol)	Not Available
Vapour pressure (kPa)	Not Applicable	Gas group	Not Available
Solubility in water (g/L)	Partly miscible	pH as a solution (1%)	Not Available

Continued...

Dentsply Jeltrate Alginate Impression Material

Vapour density (Air = 1) Not Applicable

VOC g/L Not Available

SECTION 10 STABILITY AND REACTIVITY

Reactivity	See section 7
Chemical stability	<ul style="list-style-type: none"> Unstable in the presence of incompatible materials. Product is considered stable. Hazardous polymerisation will not occur.
Possibility of hazardous reactions	See section 7
Conditions to avoid	See section 7
Incompatible materials	See section 7
Hazardous decomposition products	See section 5

SECTION 11 TOXICOLOGICAL INFORMATION

Information on toxicological effects

Inhaled	<p>The material can cause respiratory irritation in some persons. The body's response to such irritation can cause further lung damage. Inhalation of dusts, generated by the material during the course of normal handling, may be damaging to the health of the individual. Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.</p> <p>If prior damage to the circulatory or nervous systems has occurred or if kidney damage has been sustained, proper screenings should be conducted on individuals who may be exposed to further risk if handling and use of the material result in excessive exposures.</p> <p>Effects on lungs are significantly enhanced in the presence of respirable particles. Acute silicosis occurs under conditions of extremely high silica dust exposure particularly when the particle size of the dust is small. The disease is rapidly progressive and spreads widely through the lungs within months of the initial exposure and causing death within 1 to 2 years.</p>
Ingestion	<p>The material has NOT been classified by EC Directives or other classification systems as "harmful by ingestion". This is because of the lack of corroborating animal or human evidence.</p> <p>Not normally a hazard due to the physical form of product. The material is a physical irritant to the gastro-intestinal tract</p>
Skin Contact	<p>Four students received severe hand burns whilst making moulds of their hands with dental plaster substituted for Plaster of Paris. The dental plaster known as "Stone" was a special form of calcium sulfate hemihydrate containing alpha-hemihydrate crystals that provide high compression strength to the moulds. Beta-hemihydrate (normal Plaster of Paris) does not cause skin burns in similar circumstances.</p> <p>Irritation and skin reactions are possible with sensitive skin</p> <p>Open cuts, abraded or irritated skin should not be exposed to this material</p> <p>Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.</p>
Eye	This material can cause eye irritation and damage in some persons.
Chronic	<p>Long-term exposure to respiratory irritants may result in airways disease, involving difficulty breathing and related whole-body problems. Harmful: danger of serious damage to health by prolonged exposure through inhalation.</p> <p>This material can cause serious damage if one is exposed to it for long periods. It can be assumed that it contains a substance which can produce severe defects.</p> <p>Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure. There has been some concern that this material can cause cancer or mutations but there is not enough data to make an assessment.</p> <p>In a case of chronic abuse of magnesium citrate, symptoms seen included tiredness and severe low blood pressure which did not respond to treatment. Blood tests revealed extremely high levels of magnesium, and the patient was found to have a perforated ulcer of the duodenum. Kidney failure and death followed.</p> <p>A patient with normal kidney function developed stoppage of breathing and slow heart rate after receiving 90 grams of magnesium sulfate over 18 hours. Crystalline silicas activate the inflammatory response of white blood cells after they injure the lung epithelium. Chronic exposure to crystalline silicas reduces lung capacity and predisposes to chest infections.</p> <p>Overexposure to the breathable dust may cause coughing, wheezing, difficulty in breathing and impaired lung function. Chronic symptoms may include decreased vital lung capacity and chest infections. Repeated exposures in the workplace to high levels of fine-divided dusts may produce a condition known as pneumoconiosis, which is the lodgement of any inhaled dusts in the lung, irrespective of the effect. This is particularly true when a significant number of particles less than 0.5 microns (1/50000 inch) are present.</p> <p>Amorphous silicas generally are less hazardous than crystalline silicas, but the former can be converted to the latter on heating and subsequent cooling. Inhalation of dusts containing crystalline silicas may lead to silicosis, a disabling lung disease that may take years to develop.</p>

Dentsply Jeltrate Alginate Impression Material	TOXICITY	IRRITATION
	Not Available	Not Available
diatomaceous earth, flux-calcined	TOXICITY	IRRITATION
	Oral (rat) LD50: >2000 mg/kg ^[1]	Not Available
cristobalite	TOXICITY	IRRITATION
	Not Available	Not Available
calcium sulfate	TOXICITY	IRRITATION
	Oral (rat) LD50: >1581 mg/kg ^[1]	Not Available
magnesium oxide	TOXICITY	IRRITATION
	Not Available	Not Available

Dentsply Jeltrate Alginate Impression Material

silica crystalline - quartz	TOXICITY	IRRITATION
	Not Available	Not Available
tetrasodium pyrophosphate	TOXICITY	IRRITATION
	Dermal (rabbit) LD50: >300 mg/kg ^[1] Oral (rat) LD50: ~1624 mg/kg ^[1]	Not Available
Yellow Iron Oxide	TOXICITY	IRRITATION
	Not Available	Not Available
D&C Red No.30 Aluminium Lake	TOXICITY	IRRITATION
	Not Available	Not Available

Legend: 1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. * Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances

CRISTOBALITE	Inhalation (human) TCLo: 16 mppcf*8H/17.9y-l * Millions of particles per cubic foot
CALCIUM SULFATE	Gypsum (calcium sulfate dehydrate) irritates the skin, eye, mucous membranes, and airways. A series of studies involving Gypsum industry workers in Poland reported chronic, non-specific airways diseases. Repeat dose toxicity: Examination of workers at a gypsum manufacturing plant found restrictive defects on long-function tests in those who were chronically exposed to gypsum dust. Synergistic/antagonistic effects: Gypsum appears to be protective on quartz toxicity in animal testing.
MAGNESIUM OXIDE	The following information refers to contact allergens as a group and may not be specific to this product. Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's oedema. The pathogenesis of contact eczema involves a cell-mediated (T lymphocytes) immune reaction of the delayed type. Other allergic skin reactions, e.g. contact urticaria, involve antibody-mediated immune reactions.
Dentsply Jeltrate Alginate Impression Material & CALCIUM SULFATE & MAGNESIUM OXIDE & TETRASODIUM PYROPHOSPHATE	Asthma-like symptoms may continue for months or even years after exposure to the material ends. This may be due to a non-allergic condition known as reactive airways dysfunction syndrome (RADS) which can occur after exposure to high levels of highly irritating compound. Main criteria for diagnosing RADS include the absence of previous airways disease in a non-atopic individual, with sudden onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. Other criteria for diagnosis of RADS include a reversible airflow pattern on lung function tests, moderate to severe bronchial hyperreactivity on methacholine challenge testing, and the lack of minimal lymphocytic inflammation, without eosinophilia.
Dentsply Jeltrate Alginate Impression Material & D&C RED NO.30 ALUMINIUM LAKE	No significant acute toxicological data identified in literature search.
Dentsply Jeltrate Alginate Impression Material & DIATOMACEOUS EARTH, FLUX-CALCINED	For silica amorphous: When experimental animals inhale synthetic amorphous silica (SAS) dust, it dissolves in the lung fluid and is rapidly eliminated. If swallowed, the vast majority of SAS is excreted in the faeces and there is little accumulation in the body. Following absorption across the gut, SAS is eliminated via urine without modification in animals and humans. SAS is not expected to be broken down (metabolised) in mammals.
CRISTOBALITE & SILICA CRYSTALLINE - QUARTZ	WARNING: For inhalation exposure <u>ONLY</u> : This substance has been classified by the IARC as Group 1: CARCINOGENIC TO HUMANS
CRISTOBALITE & SILICA CRYSTALLINE - QUARTZ	The International Agency for Research on Cancer (IARC) has classified occupational exposures to respirable (<5 um) crystalline silica as being carcinogenic to humans. This classification is based on what IARC considered sufficient evidence from epidemiological studies of humans for the carcinogenicity of inhaled silica in the forms of quartz and cristobalite. Crystalline silica is also known to cause silicosis, a non-cancerous lung disease. Intermittent exposure produces; focal fibrosis, (pneumoconiosis), cough, dyspnoea, liver tumours.

Acute Toxicity	☐	Carcinogenicity	✓
Skin Irritation/Corrosion	☐	Reproductivity	☐
Serious Eye Damage/Irritation	✓	STOT - Single Exposure	✓
Respiratory or Skin sensitisation	✓	STOT - Repeated Exposure	✓
Mutagenicity	✓	Aspiration Hazard	☐

Legend: ✗ – Data available but does not fill the criteria for classification
 ✓ – Data available to make classification
 ☐ – Data Not Available to make classification

SECTION 12 ECOLOGICAL INFORMATION

Toxicity

Dentsply Jeltrate Alginate Impression Material	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	Not Available	Not Available	Not Available	Not Available	Not Available
diatomaceous earth, flux-calcined	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	Not Available	Not Available	Not Available	Not Available	Not Available
cristobalite	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE

Continued...

Dentsply Jeltrate Alginate Impression Material

	Not Available	Not Available	Not Available	Not Available	Not Available
calcium sulfate	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	LC50	96	Fish	>1970mg/L	4
	EC50	96	Algae or other aquatic plants	3200mg/L	4
	EC0	96	Crustacea	=1255.000mg/L	1
	NOEC	504	Crustacea	360mg/L	4
magnesium oxide	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	Not Available	Not Available	Not Available	Not Available	Not Available
silica crystalline - quartz	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	Not Available	Not Available	Not Available	Not Available	Not Available
tetrasodium pyrophosphate	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	LC50	96	Fish	1380mg/L	4
Yellow Iron Oxide	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	Not Available	Not Available	Not Available	Not Available	Not Available
D&C Red No.30 Aluminium Lake	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	Not Available	Not Available	Not Available	Not Available	Not Available

Legend: Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated) 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data

DO NOT discharge into sewer or waterways.

Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
calcium sulfate	HIGH	HIGH
tetrasodium pyrophosphate	HIGH	HIGH

Bioaccumulative potential

Ingredient	Bioaccumulation
calcium sulfate	LOW (LogKOW = -2.2002)
tetrasodium pyrophosphate	LOW (LogKOW = -1.7388)

Mobility in soil

Ingredient	Mobility
calcium sulfate	LOW (KOC = 6.124)
tetrasodium pyrophosphate	LOW (KOC = 7.883)

SECTION 13 DISPOSAL CONSIDERATIONS

Waste treatment methods

Product / Packaging disposal	<ul style="list-style-type: none"> Recycle wherever possible. Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified. Dispose of by: burial in a land-fill specifically licensed to accept chemical and / or pharmaceutical wastes or Incineration in a licensed apparatus (after admixture with suitable combustible material) Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.
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SECTION 14 TRANSPORT INFORMATION

Labels Required

Marine Pollutant	NO
HAZCHEM	Not Applicable

Land transport (ADG): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Continued...

Dentsply Jeltrate Alginate Impression Material

Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

SECTION 15 REGULATORY INFORMATION

Safety, health and environmental regulations / legislation specific for the substance or mixture

DIATOMACEOUS EARTH, FLUX-CALCINED(68855-54-9) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

CRISTOBALITE(14464-46-1) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Exposure Standards

Australia Hazardous Substances Information System - Consolidated Lists

Australia Inventory of Chemical Substances (AICS)

Australia Work Health and Safety Regulations 2016 - Hazardous chemicals (other than lead) requiring health monitoring

CALCIUM SULFATE(7778-18-9) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Exposure Standards

Australia Inventory of Chemical Substances (AICS)

MAGNESIUM OXIDE(1309-48-4.) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Exposure Standards

Australia Hazardous Substances Information System - Consolidated Lists

Australia Inventory of Chemical Substances (AICS)

SILICA CRYSTALLINE - QUARTZ(14808-60-7) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Exposure Standards

Australia Hazardous Substances Information System - Consolidated Lists

Australia Inventory of Chemical Substances (AICS)

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs

TETRASODIUM PYROPHOSPHATE(7722-88-5) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Exposure Standards

Australia Hazardous Substances Information System - Consolidated Lists

Australia Inventory of Chemical Substances (AICS)

YELLOW IRON OXIDE(NOT APPLICABLE) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Not Applicable

D&C RED NO.30 ALUMINIUM LAKE(1342-90-1) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Not Applicable

National Inventory	Status
Australia - AICS	N (D&C Red No.30 Aluminium Lake)
Canada - DSL	N (D&C Red No.30 Aluminium Lake)
Canada - NDSL	N (silica crystalline - quartz; diatomaceous earth, flux-calcined; tetrasodium pyrophosphate; cristobalite; magnesium oxide; calcium sulfate; D&C Red No.30 Aluminium Lake)
China - IECSC	N (D&C Red No.30 Aluminium Lake)
Europe - EINEC / ELINCS / NLP	N (D&C Red No.30 Aluminium Lake)
Japan - ENCS	N (diatomaceous earth, flux-calcined; tetrasodium pyrophosphate; D&C Red No.30 Aluminium Lake)
Korea - KECI	N (D&C Red No.30 Aluminium Lake)
New Zealand - NZIoC	N (D&C Red No.30 Aluminium Lake)
Philippines - PICCS	N (D&C Red No.30 Aluminium Lake)
USA - TSCA	N (D&C Red No.30 Aluminium Lake)
Legend:	Y = All ingredients are on the inventory N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)

SECTION 16 OTHER INFORMATION

Other information

Ingredients with multiple cas numbers

Name	CAS No
calcium sulfate	7778-18-9, 10101-41-4, 14798-04-0
silica crystalline - quartz	14808-60-7, 122304-48-7, 122304-49-8, 12425-26-2, 1317-79-9, 70594-95-5, 87347-84-0, 308075-07-2
tetrasodium pyrophosphate	7722-88-5, 13472-36-1

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

Definitions and abbreviations

Continued...

Dentsply Jeltrate Alginate Impression Material

PC—TWA: Permissible Concentration-Time Weighted Average

PC—STEL: Permissible Concentration-Short Term Exposure Limit

IARC: International Agency for Research on Cancer

ACGIH: American Conference of Governmental Industrial Hygienists

STEL: Short Term Exposure Limit

TEEL: Temporary Emergency Exposure Limit,

IDLH: Immediately Dangerous to Life or Health Concentrations

OSF: Odour Safety Factor

NOAEL :No Observed Adverse Effect Level

LOAEL: Lowest Observed Adverse Effect Level

TLV: Threshold Limit Value

LOD: Limit Of Detection

OTV: Odour Threshold Value

BCF: BioConcentration Factors

BEI: Biological Exposure Index

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TEL (+61 3) 9572 4700.

DENTSPLY Milford

Safety Data Sheet

505502

1. Identification

Product Name JELTRATE® PLUS	SDS Code Number 505502
Substance Identity JELTRATE® PLUS Alginate Impression Material	Date of Last Revision 01/18/17
Manufacturer: DENTSPLY Milford	Address 38 West Clarke Avenue Milford DE 19963-1805 http://www.dentsply.com
Grades or Minor Variant Identities Fast Set and Regular Set	Information Telephone Number (302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)
Product Use (for Canada) Dental Alginate Impression Material	Emergency Telephone Number (302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)

2. Hazard(s) Identification



WARNING
CAUSES SKIN IRRITATION

WASH HANDS THOROUGHLY AFTER HANDLING
WEAR PROTECTIVE GLOVES
IF ON SKIN: WASH WITH PLENTY OF SOAP AND WATER.
IF SKIN IRRITATION OCCURS: GET MEDICAL ADVICE / ATTENTION
TAKE OFF CONTAMINATED CLOTHING AND WASH BEFORE REUSE

3. Composition/Information on Ingredients

Hazardous Components	C.A.S. Number	Exposure Limits	%
Silicon Dioxide -Crystalline - Cristobalite	14464-46-1	0.025 mg/M ³	< than 19
Silicon Dioxide - Crystalline -Quartz	14808-60-7	0.025 mg/M ³	< than 3
Silicon Dioxide – Amorphous - Diatomaceous Earth	68855-54-9	0.1 mg/M ³	< than 26
Calcium Sulfate	10101-41-4	10 mg/M ³	< than 20
Magnesium Oxide	1309-48-4	10 mg/M ³	< than 7
Tetrasodium Pyrophosphate	7722-88-5	5 mg/M ³	< than 3

Colorant Information: Fast Set Product contains D & C Red # 30 Aluminum Lake as colorant.

Regular Set Product contains synthetic Yellow Iron Oxide as colorant.

Coating Information: The coating agent is an organic glycol compound.

Antibacterial Additive: The antibacterial additive is a quaternary ammonium compound.

4. First Aid Measures

Routes of Exposure	First Aid Instructions	Immediate Medical Attention	Delayed Effects
Eye	Rinse opened eye for several minutes under running water. If symptoms persist consult physician	Not Applicable	Not Applicable
Skin	Immediately wash with soap and water and rinse thoroughly	Not Applicable	Not Applicable
Inhalation	Supply fresh air, consult physician if symptoms persist	Not Applicable	Not Applicable
Ingestion	If symptoms persist consult physician	Not Applicable	Low order of toxicity is expected when large amounts of material are ingested. Acute toxicology study in rats LD ₅₀ >2,000mg/kg.
Other	Not Applicable	Not Applicable	Not Applicable

Note to Physicians (Treating, Testing and Monitoring): Treat symptomatically.

5. Fire Fighting Measures

Flame Propagation or Burning Rate (for Solids): Not Applicable	Properties Contributing to Fire Intensity: Not Applicable	Flammability Classification: Not Applicable	Other: Not Applicable
Extinguishing Media: CO ₂ , extinguishing powder, foam carbon dioxide or water spray. Fight larger fires with water spray or alcohol resistant foam.		Extinguishing Media to Avoid: Water with full jet.	

Protection and Procedures for Firefighters: Firefighters should wear self-contained respiratory protective devices.
Unusual Fire and Explosion Hazards: No dangerous decomposition products known. - Product does not present an explosion hazard.

6. Accidental Release Measures

Containment Techniques: Material is a dry fluffy powder, which is colored pale yellow or pink. Store only in the original package. Keep package tightly sealed to minimize dust generation and accumulation. The avoidance of any air contaminant is always a recommended practice. Adherence to work place ventilation standards is an assurance of general personnel health and comfort		
Spill/Leak Clean-up Procedures and Equipment: Wear protective clothing and scoop up bulk material and place in a labeled plastic or metal container. Avoid gross skin contact to minimize the possibility of drying out the skin. Ensure adequate ventilation, by either natural or mechanical means to keep dust level below PEL.		
Evacuation Procedures: Not Applicable	Special Instructions: Not Applicable	Reporting Requirements: Not Applicable

7. Handling and Storage

Handling Practices and Warnings: Product is intended for dental use only. Handling of this product should be by trained dental healthcare professionals only. Observe normal care for working with chemicals.
Storage Practices and Warnings: Store only in the original package. Keep package tightly sealed. Store in a dry area. Protect from exposure to direct light. Store in a cool dry area. Store away from food and beverages. Minimize dust generation and accumulation. Avoid breathing dust and contact with eyes. Return cap to canisters immediately. Close pouches immediately after use. Continue to follow all SDS/label warnings when handling empty containers. Observe normal warehouse handling procedures. The avoidance of any air contaminant is always a recommended practice. Adherence to work place ventilation standards is an assurance of general personnel health and comfort.

8. Exposure Control / Personal Protection



Individual Protection Measures	Personal Protective Equipment for Normal Use	Personal Protective Equipment for Emergencies
Eye/Face	Safety Glasses	Not Applicable
Skin	The glove material has to be impermeable and resistant to the product.	Not Applicable
Inhalation	Recommended NIOSH approved nuisance dust mask. <10X PEL, use 3M 9900; <100X PEL, use MSA Ultra-Twin with H filter; <200X PEL, use MSA 01-00-06 with type C supplied air unit (continuous flow mode); or equivalent. Use sufficient natural or mechanical ventilation to keep dust level below PEL.	Not Applicable
Body Protection	Protective work clothing such as lab coat.	Not Applicable
General Hygiene Considerations and Work Practices: Avoid dusting when in use. Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at end of work. Avoid contact with the eyes and skin. Do not eat, drink or smoke when using.		
Protective Measures During Repair and Maintenance of Contaminated Equipment: Not Applicable		
Other Protective Measures and Equipment: Not Applicable		

9. Physical and Chemical Characteristics

Appearance: Dry fluffy powder. May be colored pale yellow or pink.	Odor: Spearmint odor.
Normal Physical State: Dry fluffy powder.	Melting Point: Not Applicable
Specific Gravity: 0.3 g/cm ³	Solubility in Water: Partially soluble
Vapor Pressure (mm Hg): Not Applicable	pH: Not Applicable
Other: Not Applicable	Vapor Density (AIR=1):
	Evaporation Rate (Butyl Acetate =1): Not Applicable

10. Stability and Reactivity Data

Incompatibility (Materials to Avoid): Hydrofluoric Acid.	
Hazardous Products Produced During Decomposition: No dangerous decomposition products known if used according to Directions for Use. (DFU).	
Hazardous Polymerization: <input type="checkbox"/> May Occur <input checked="" type="checkbox"/> May Not Occur	Conditions to Avoid: None known
Stability? <input checked="" type="checkbox"/> Stable <input type="checkbox"/> Unstable	Conditions to Avoid: None known

11. Toxicological Information

Toxicity Data, Epidemiology Studies, Carcinogenicity, Neurological Effects, Genetic Effects, Reproductive Effects, or Structure Activity Data: Product may irritate the skin. On the eye the product has an irritating effect. Sensitization: No sensitizing effects known.					
Emergency Overview: Material may be mildly irritating to eyes.					
Routes of Exposure	Signs and Symptoms	Single, Repeated, or Lifetime Exposure	Severity (Mild, Moderate, Severe)	Acute and Chronic Health Effect(s)	Target Organ(s)
Eye	Material can cause irritation.	Single	Moderate	Irritation and possible corneal damage	Not Applicable
Skin	Material may be irritating	Single & Repeated	Moderate	Possible irritation	Not Applicable
Inhalation	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Ingestion	Material is probably not harmful if swallowed	Not Applicable	Mild	Low order of toxicity is expected when large amounts of material are ingested. Acute toxicology study in rats LD ₅₀ >2,000mg/kg.	Not Applicable
Other	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable

Medical Conditions Aggravated by Exposure Open sores and wounds of the skin.			
Carcinogenicity	NTP?: Not listed	IARC monographs?: Not listed	OSHA regulated?: No All components of this product are in compliance with the inventory listing Requirements of the U. S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory.
Potential Environmental Effects Do not allow to enter sewers/ surface or ground water.			
NFPA Hazard Classification Ratings (Scale 0-4), Health = 0, Fire = 0, Reactivity = 0			

12. Ecological Information

Toxicity Data, Environmental Fate, Physical/Chemical Data, or other Data Supporting Environmental Hazard Statements: Water Hazard class1 (Self-assessment): slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water streams or sewage system.

13. Disposal Considerations

Regulations: Dispose of material as solid waste in a closed container. Dispose of in accordance with Federal, State and Local regulations. Vacuum clean dust with equipment fitted with a HEPA filter. Use dust suppression such as water if sweeping is necessary. Sweep up spilled material and place in closed containers for disposal.
Properties (Physical/Chemical) Affecting Disposal: Dispose of material as solid waste in a closed container.

14. Transport Information

Regulated for Shipping: No. Not Regulated	DOT Shipping Name: Not Regulated	Packing Group: Not Applicable
Do Changes in Quantities, packaging, or shipment method change product classification? No	DOT Hazard Class: Not Applicable	UN Number: Not Applicable

15. Regulatory Information

This product has been classified in accordance with the hazard criteria of the Globally Harmonized System of Classification and Labeling of Chemicals and the SDS contains all of the information required by the Canadian Controlled Products Regulations.
U.S. Federal Regulations: <u>CERCLA 103 Reportable Quantity</u> : This product is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations
<u>Section 313 Toxic Chemicals</u> : This product contains the following chemicals subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372): None
Section 302 Extremely Hazardous Substances (TPQ): None
<u>EPA Toxic Substances Control Act (TSCA) Status</u> : All of the components of this product are listed on the TSCA inventory.
<u>U.S. State Regulations California Proposition 65</u> : This product does not contain any chemicals, which are on the California Proposition 65 list.
<u>International Regulations: Canadian Environmental Protection Act</u> : This product is a medical device and not subject to chemical notification requirements.
<u>European Community Labeling</u> : Not a dangerous preparation.
<u>European Inventory of New and Existing Chemicals Substances (EINECS)</u> : This product is a medical device and not subject to chemical notification requirements.
Other: Not Applicable

16. Other Information

To the best of our knowledge this product does not contain gluten, wheat grains, flaxseed, natural rubber, or natural latex. All components are synthetically produced; none are derived from animal products. This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific products 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 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.
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