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.

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	0 = Minimui	m
Body Contact	2	1 = Low 2 = Modera	+0
Reactivity	1	3 = High	ıc
Chronic	3	4 = Extreme	ì

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)





SIGNAL WORD	DANGER

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.	
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	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.

SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

Substances

See section below for composition of Mixtures

Mixtures

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

SECTION 4 FIRST AID MEASURES

Description of first aid measures

Eye Contact	If this product comes in contact with the eyes: 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: ► Flush skin and hair with running water (and soap if available). ► Seek medical attention in event of irritation.
Inhalation	 If furnes 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	 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

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- ▶ 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
dvice for firefighters	
Fire Fighting	 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.
	 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. Combustion products include:
Fire/Explosion Hazard	carbon monoxide (CO) , carbon dioxide (CO2) , sulfur oxides (SOx)
	silicon dioxide (SiO2) , metal oxides , other pyrolysis products typical of burning organic material. May emit poisonous furnes. May emit corrosive furnes.
HAZCHEM	Not Applicable

SECTION 6 ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

See section 8

Environmental precautions

Methods and material for containment and cleaning up

Minor Spills	 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	Moderate hazard. 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 ► 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. Safe handling ▶ 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. ▶ Store in original containers. ► Keep containers securely sealed. Other information 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

- ► Polyethylene or polypropylene container.
- ► Check all containers are clearly labelled and free from leaks.

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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
- re 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)

Storage incompatibility

INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Australia Exposure Standards	cristobalite	Cristobalite (respirable dust)	0.1 mg/m3	Not Available	Not Available	Not Available
Australia Exposure Standards	cristobalite	Cristobalite (respirable dust)	0.1 mg/m3	Not Available	Not Available	Not Available
Australia Exposure Standards	calcium sulfate	Calcium sulphate	10 mg/m3	Not Available	Not Available	Not Available
Australia Exposure Standards	magnesium oxide	Magnesium oxide (fume)	10 mg/m3	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/m3	Not Available	Not Available	Not Available
Australia Exposure Standards	silica crystalline - quartz	Quartz (respirable dust)	0.1 mg/m3	Not Available	Not Available	Not Available
Australia Exposure Standards	tetrasodium pyrophosphate	Tetrasodium pyrophosphate	5 mg/m3	Not Available	Not Available	Not Available

EMERGENCY LIMITS

Ingredient	Material name	TEEL-1	TEEL-2	TEEL-3
cristobalite	Cristobalite	0.075 mg/m3	33 mg/m3	200 mg/m3
calcium sulfate	Calcium(II) sulfate dihydrate (1:1:2)	30 mg/m3	330 mg/m3	2,000 mg/m3
calcium sulfate	Calcium sulfate anhydrous; (Drierite; Gypsum; Plaster of Paris)	30 mg/m3	330 mg/m3	2,000 mg/m3
magnesium oxide	Magnesium oxide	30 mg/m3	120 mg/m3	730 mg/m3
silica crystalline - quartz	Silica, crystalline-quartz; (Silicon dioxide)	0.075 mg/m3	33 mg/m3	200 mg/m3
tetrasodium pyrophosphate	Sodium pyrophosphate decahydrate	8.6 mg/m3	96 mg/m3	580 mg/m3
tetrasodium pyrophosphate	Tetrasodium pyrophosphate	15 mg/m3	130 mg/m3	790 mg/m3

Ingredient	Original IDLH	Revised IDLH
diatomaceous earth, flux-calcined	Not Available	Not Available
cristobalite	25 mg/m3	Not Available
calcium sulfate	Not Available	Not Available
magnesium oxide	750 mg/m3	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

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.

The basic types of engineering controls are: Process controls which involve changing the way a job activity or process is done to reduce the risk.

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.

Personal protection











Safety glasses with side shields Chemical goggles

Eye and face protection

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	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. 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. Personal hygiene is a key element of effective hand care. Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present. Polychloroprene. In hittle rubber.
Body protection	See Other protection below
Other protection	► 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	

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Vapour density (Air = 1) Not Applicable VOC g/L Not Available

SECTION 10 STABILITY AND REACTIVITY

Reactivity	See section 7
Reactivity	OCC SCOROLLY
Chemical stability	 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

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.

Inhaled

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.

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.

Ingestion

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.

Not normally a hazard due to the physical form of product. The material is a physical irritant to the gastro-intestinal tract

Skin Contact

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.

Irritation and skin reactions are possible with sensitive skin

Open cuts, abraded or irritated skin should not be exposed to this material

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.

Eye

Chronic

This material can cause eye irritation and damage in some persons.

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.

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.

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.

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.

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.

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.

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.

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

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

Legend:

Not Available

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

Not Available

CRISTOBALITE Inhalation (human) TCLo: 16 mppcf*/8H/17.9y-I * Millions of particles per cubic foot 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 CALCIUM SULFATE 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. 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 MAGNESIUM OXIDE involves a cell-mediated (T lymphocytes) immune reaction of the delayed type. Other allergic skin reactions, e.g. contact urticaria, involve antibody-mediated **Dentsply Jeltrate Alginate** 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 Impression Material & reactive airways dysfunction syndrome (RADS) which can occur after exposure to high levels of highly irritating compound. Main criteria for diagnosing CALCIUM SULFATE & RADS include the absence of previous airways disease in a non-atopic individual, with sudden onset of persistent asthma-like symptoms within minutes to **MAGNESIUM OXIDE &** 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 **TETRASODIUM** severe bronchial hyperreactivity on methacholine challenge testing, and the lack of minimal lymphocytic inflammation, without eosinophilia. **PYROPHOSPHATE Dentsply Jeltrate Alginate** Impression Material & D&C No significant acute toxicological data identified in literature search. **RED NO.30 ALUMINIUM LAKE** For silica amorphous:

Dentsply Jeltrate Alginate Impression Material & DIATOMACEOUS EARTH, FLUX-CALCINED

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 ONLY: 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	0	Carcinogenicity	✓
Skin Irritation/Corrosion	0	Reproductivity	0
Serious Eye Damage/Irritation	✓	STOT - Single Exposure	✓
Respiratory or Skin sensitisation	✓	STOT - Repeated Exposure	~
Mutagenicity	✓	Aspiration Hazard	0

Legend:

Data available to make classification

O - 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 Not Available Available
	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE SOURCE
diatomaceous earth, flux-calcined	Not Available	Not Available	Not Available	Not Not Available Available
	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE SOURCE
cristobalite				

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

- ► 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.

SECTION 14 TRANSPORT INFORMATION

Labels Required

Marine Pollutant	NO
HAZCHEM	Not Applicable

Dentsply Jeltrate Alginate Impression Material

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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

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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 Inventory of Chemical Substances (AICS)
Australia Hazardous Substances Information System - Consolidated Lists	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 Inventory of Chemical Substances (AICS)

Australia Hazardous Substances Information System - Consolidated Lists

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

Australia Exposure Standards	Australia Inventory of Chemical Substances (AICS)
Australia Hazardous Substances Information System - Consolidated Lists	International Agency for Research on Cancer (IARC) - Agents Classified by the IARC
	Managrapha

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

Australia Exposure Standards

Australia Inventory of Chemical Substances (AICS)

Australia Hazardous Substances Information System - Consolidated Lists

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

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Dentsply Jeltrate Alginate Impression Material

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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

BEI: Biological Exposure Index This document is copyright.

BCF: BioConcentration Factors

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