

# Dentsply Regisil - Regisil 2X - Regisil PB - Regisil Rigid

Dentsply Sirona Pty Ltd

Chemwatch Hazard Alert Code: 3

Chemwatch: 4993-58

Version No: 4.1.1.1

Safety Data Sheet according to WHS and ADG requirements

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S.GHS.AUS.EN

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

### Product Identifier

Product name	Dentsply Regisil - Regisil 2X - Regisil PB - Regisil Rigid
Synonyms	Vinyl Polysiloxane Bite Registration Material, Part number: 619100 - 619999
Other means of identification	Not Available

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

Relevant identified uses	For dental use only
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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	1		
Body Contact	2		
Reactivity	1		
Chronic	3		

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

Poisons Schedule	Not Applicable
Classification <sup>[1]</sup>	Eye Irritation Category 2A, Carcinogenicity Category 1A, Specific target organ toxicity - single exposure Category 3 (respiratory tract irritation)
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	<b>DANGER</b>

### Hazard statement(s)

H319	Causes serious eye irritation.
H350	May cause cancer.
H335	May cause respiratory irritation.

### Precautionary statement(s) Prevention

P201	Obtain special instructions before use.
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Continued...

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P271	Use only outdoors or in a well-ventilated area.
P281	Use personal protective equipment as required.
P261	Avoid breathing mist/vapours/spray.

## Precautionary statement(s) Response

P308+P313	IF exposed or concerned: Get medical advice/attention.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P312	Call a POISON CENTER or doctor/physician if you feel unwell.
P337+P313	If eye irritation persists: Get medical advice/attention.

## 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
68083-19-2	30-60	<u>dimethylsiloxane, vinyl-terminated</u>
7778-18-9	5-30	<u>calcium sulfate</u>
7631-86-9	5-30	<u>silica amorphous</u>
14464-46-1	5-30	<u>crystalobalite</u>
68037-59-2	5-15	<u>dimethylsiloxane, methylhydrogen-</u>
68611-44-9	<10	<u>silica amorphous, fumed</u>
13463-67-7	<5	<u>titanium dioxide</u>
68515-40-2	<5	<u>benzyl-C7-C8-alkyl phthalate</u>
Not Available	<5	organo platinum complex
39277-28-6	<2	<u>ar-tosylamide/ formaldehyde/ melamine polymer</u>
12769-96-9	<2	<u>C.I. Pigment Violet 15</u>

## SECTION 4 FIRST AID MEASURES

## Description of first aid measures

<b>Eye Contact</b>	<p>If this product comes in contact with the eyes:</p> <ul style="list-style-type: none"> <li>▶ Immediately hold eyelids apart and flush the eye continuously with running water.</li> <li>▶ 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.</li> <li>▶ Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes.</li> <li>▶ Transport to hospital or doctor without delay.</li> <li>▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.</li> </ul>
<b>Skin Contact</b>	<p>If skin or hair contact occurs:</p> <ul style="list-style-type: none"> <li>▶ Immediately flush body and clothes with large amounts of water, using safety shower if available.</li> <li>▶ Quickly remove all contaminated clothing, including footwear.</li> <li>▶ Wash skin and hair with running water. Continue flushing with water until advised to stop by the Poisons Information Centre.</li> <li>▶ Transport to hospital, or doctor.</li> </ul>
<b>Inhalation</b>	<ul style="list-style-type: none"> <li>▶ If fumes, aerosols or combustion products are inhaled remove from contaminated area.</li> <li>▶ Other measures are usually unnecessary.</li> </ul>
<b>Ingestion</b>	<ul style="list-style-type: none"> <li>▶ Immediately give a glass of water.</li> <li>▶ First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.</li> </ul>

## Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

## SECTION 5 FIREFIGHTING MEASURES

## Extinguishing media

- ▶ Foam.
- ▶ Dry chemical powder.
- ▶ BCF (where regulations permit).
- ▶ Carbon dioxide.

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## Special hazards arising from the substrate or mixture

<b>Fire Incompatibility</b>	<ul style="list-style-type: none"> <li>▶ Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result</li> </ul>
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## Advice for firefighters

<b>Fire Fighting</b>	<ul style="list-style-type: none"> <li>▶ Alert Fire Brigade and tell them location and nature of hazard.</li> <li>▶ Wear breathing apparatus plus protective gloves.</li> <li>▶ Prevent, by any means available, spillage from entering drains or water courses.</li> <li>▶ Use water delivered as a fine spray to control fire and cool adjacent area.</li> </ul>
<b>Fire/Explosion Hazard</b>	<ul style="list-style-type: none"> <li>▶ High temperature decomposition products include silicon dioxide, small amounts of formaldehyde, formic acid, acetic acid and traces of silicon polymers.</li> <li>▶ These gases may ignite and, depending on circumstances, may cause the resin/polymer to ignite.</li> <li>▶ An outer skin of silica may also form. Extinguishing of fire, beneath the skin, may be difficult.</li> <li>▶ Combustible.</li> <li>▶ Slight fire hazard when exposed to heat or flame.</li> <li>▶ Heating may cause expansion or decomposition leading to violent rupture of containers.</li> <li>▶ On combustion, may emit toxic fumes of carbon monoxide (CO).</li> </ul> <p>Combustion products include:</p> <ul style="list-style-type: none"> <li>• carbon dioxide (CO<sub>2</sub>)</li> <li>• carbon monoxide (CO)</li> <li>• silicon dioxide (SiO<sub>2</sub>)</li> <li>• metal oxides</li> <li>• other pyrolysis products typical of burning organic material.</li> </ul> <p>May emit poisonous fumes. May emit corrosive fumes.</p>
<b>HAZCHEM</b>	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

<b>Minor Spills</b>	<p>Slippery when spilt.</p> <ul style="list-style-type: none"> <li>▶ Clean up all spills immediately.</li> <li>▶ Avoid breathing vapours and contact with skin and eyes.</li> <li>▶ Control personal contact with the substance, by using protective equipment.</li> <li>▶ Contain and absorb spill with sand, earth, inert material or vermiculite.</li> </ul>
<b>Major Spills</b>	<p>Slippery when spilt. Minor hazard.</p> <ul style="list-style-type: none"> <li>▶ Clear area of personnel.</li> <li>▶ Alert Fire Brigade and tell them location and nature of hazard.</li> <li>▶ Control personal contact with the substance, by using protective equipment as required.</li> </ul>

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

## SECTION 7 HANDLING AND STORAGE

## Precautions for safe handling

<b>Safe handling</b>	<ul style="list-style-type: none"> <li>▶ Avoid all personal contact, including inhalation.</li> <li>▶ Wear protective clothing when risk of exposure occurs.</li> <li>▶ Use in a well-ventilated area.</li> <li>▶ Prevent concentration in hollows and sumps.</li> </ul>
<b>Other information</b>	<ul style="list-style-type: none"> <li>▶ Store in original containers.</li> <li>▶ Keep containers securely sealed.</li> <li>▶ Store in a cool, dry, well-ventilated area.</li> <li>▶ Store away from incompatible materials and foodstuff containers.</li> </ul> <p><b>DO NOT store above 60 deg. C.</b></p>

## Conditions for safe storage, including any incompatibilities

<b>Suitable container</b>	<ul style="list-style-type: none"> <li>▶ Polyethylene or polypropylene container.</li> <li>▶ Packing as recommended by manufacturer.</li> <li>▶ Check all containers are clearly labelled and free from leaks.</li> </ul>
<b>Storage incompatibility</b>	<ul style="list-style-type: none"> <li>▶ Avoid reaction with oxidising agents (condensation silicones, tin and sulfur, amines and peroxides).</li> </ul>

## SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

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## Control parameters

## OCCUPATIONAL EXPOSURE LIMITS (OEL)

## INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Australia Exposure Standards	calcium sulfate	Calcium sulphate	10 mg/m3	Not Available	Not Available	Not Available
Australia Exposure Standards	silica amorphous	Fumed silica (respirable dust)	2 mg/m3	Not Available	Not Available	Not Available
Australia Exposure Standards	silica amorphous	Fumed silica (respirable dust)	2 mg/m3	Not Available	Not Available	Not Available
Australia Exposure Standards	silica amorphous	Diatomaceous earth (uncalcined)	10 mg/m3	Not Available	Not Available	Not Available
Australia Exposure Standards	silica amorphous	Diatomaceous earth (uncalcined)	10 mg/m3	Not Available	Not Available	Not Available
Australia Exposure Standards	silica amorphous	Silica gel	10 mg/m3	Not Available	Not Available	Not Available
Australia Exposure Standards	silica amorphous	Silica, fused	Not Available	Not Available	Not Available	Not Available
Australia Exposure Standards	silica amorphous	Precipitated silica	10 mg/m3	Not Available	Not Available	Not Available
Australia Exposure Standards	silica amorphous	Precipitated silica	10 mg/m3	Not Available	Not Available	Not Available
Australia Exposure Standards	silica amorphous	Silica gel	10 mg/m3	Not Available	Not Available	Not Available
Australia Exposure Standards	crystalite	Cristobalite (respirable dust)	0.1 mg/m3	Not Available	Not Available	Not Available
Australia Exposure Standards	crystalite	Cristobalite (respirable dust)	0.1 mg/m3	Not Available	Not Available	Not Available
Australia Exposure Standards	titanium dioxide	Titanium dioxide	10 mg/m3	Not Available	Not Available	Not Available

## EMERGENCY LIMITS

Ingredient	Material name	TEEL-1	TEEL-2	TEEL-3
dimethylsiloxane, vinyl-terminated	Poly(dimethylsiloxane), vinyl dimethylsiloxy terminated	48 mg/m3	530 mg/m3	3,200 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
silica amorphous	Silica gel, amorphous synthetic	18 mg/m3	200 mg/m3	1,200 mg/m3
silica amorphous	Silica, amorphous fumed	18 mg/m3	100 mg/m3	630 mg/m3
silica amorphous	Siloxanes and silicones, dimethyl, reaction products with silica; (Hydrophobic silicon dioxide, amorphous)	120 mg/m3	1,300 mg/m3	7,900 mg/m3
silica amorphous	Silica, amorphous fume	45 mg/m3	500 mg/m3	3,000 mg/m3
silica amorphous	Silica amorphous hydrated	18 mg/m3	220 mg/m3	1,300 mg/m3
crystalite	Cristobalite	0.075 mg/m3	33 mg/m3	200 mg/m3
dimethylsiloxane, methylhydrogen-	Methylhydrosiloxane (3-4%) + dimethylsiloxane (96-97%) copolymer	30 mg/m3	330 mg/m3	2,000 mg/m3
silica amorphous, fumed	Silica, amorphous fumed	18 mg/m3	100 mg/m3	630 mg/m3
titanium dioxide	Titanium oxide; (Titanium dioxide)	30 mg/m3	330 mg/m3	2,000 mg/m3

Ingredient	Original IDLH	Revised IDLH
dimethylsiloxane, vinyl-terminated	Not Available	Not Available
calcium sulfate	Not Available	Not Available
silica amorphous	3000 mg/m3	Not Available
crystalite	25 mg/m3	Not Available
dimethylsiloxane, methylhydrogen-	Not Available	Not Available
silica amorphous, fumed	3000 mg/m3	Not Available
titanium dioxide	5000 mg/m3	Not Available
benzyl-C7-C8-alkyl phthalate	Not Available	Not Available
organo platinum complex	Not Available	Not Available
ar-tosylamide/ formaldehyde/ melamine polymer	Not Available	Not Available
C.I. Pigment Violet 15	Not Available	Not Available

## Exposure controls

## Appropriate engineering controls

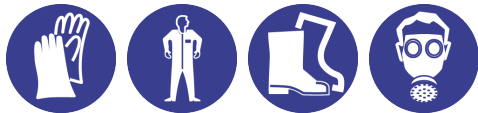
Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection.

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.

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<b>Personal protection</b>	
<b>Eye and face protection</b>	<ul style="list-style-type: none"> <li>▶ Chemical goggles.</li> <li>▶ Full face shield may be required for supplementary but never for primary protection of eyes.</li> <li>▶ 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.</li> </ul>
<b>Skin protection</b>	See Hand protection below
<b>Hands/feet protection</b>	Wear protective gloves, e.g. PVC. <ul style="list-style-type: none"> <li>▶ Wear chemical protective gloves, e.g. PVC.</li> <li>▶ Wear safety footwear or safety gumboots, e.g. Rubber   Latex or rubber gloves may inhibit set.</li> </ul>
<b>Body protection</b>	See Other protection below
<b>Other protection</b>	<ul style="list-style-type: none"> <li>▶ Overalls.</li> <li>▶ P.V.C. apron.</li> <li>▶ Barrier cream.</li> </ul>
<b>Thermal hazards</b>	Not Available

**Respiratory protection**

Type A-P Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

Where the concentration of gas/particulates in the breathing zone, approaches or exceeds the "Exposure Standard" (or ES), respiratory protection is required. Degree of protection varies with both face-piece and Class of filter; the nature of protection varies with Type of filter.

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	A-AUS P2	-	A-PAPR-AUS / Class 1 P2
up to 50 x ES	-	A-AUS / Class 1 P2	-
up to 100 x ES	-	A-2 P2	A-PAPR-2 P2 ^

^ - Full-face

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(SO<sub>2</sub>), G = Agricultural chemicals, K = Ammonia(NH<sub>3</sub>), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

**SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES****Information on basic physical and chemical properties**

<b>Appearance</b>	Various coloured pastes with faint sweet odour; does not mix with water		
<b>Physical state</b>	Non Slump Paste	<b>Relative density (Water = 1)</b>	1.2 (1.6 for PB & Rigid)
<b>Odour</b>	Not Available	<b>Partition coefficient n-octanol / water</b>	Not Available
<b>Odour threshold</b>	Not Available	<b>Auto-ignition temperature (°C)</b>	Not Available
<b>pH (as supplied)</b>	Not Available	<b>Decomposition temperature</b>	Not Available
<b>Melting point / freezing point (°C)</b>	Not Available	<b>Viscosity (cSt)</b>	Not Available
<b>Initial boiling point and boiling range (°C)</b>	>200	<b>Molecular weight (g/mol)</b>	Not Applicable
<b>Flash point (°C)</b>	>213 (cc)	<b>Taste</b>	Not Available
<b>Evaporation rate</b>	<1	<b>Explosive properties</b>	Not Available
<b>Flammability</b>	Not Applicable	<b>Oxidising properties</b>	Not Available
<b>Upper Explosive Limit (%)</b>	Not Available	<b>Surface Tension (dyn/cm or mN/m)</b>	Not Available
<b>Lower Explosive Limit (%)</b>	Not Available	<b>Volatile Component (%vol)</b>	Not Available
<b>Vapour pressure (kPa)</b>	Not Applicable	<b>Gas group</b>	Not Available
<b>Solubility in water (g/L)</b>	Immiscible	<b>pH as a solution (1%)</b>	Not Available
<b>Vapour density (Air = 1)</b>	Not Applicable	<b>VOC g/L</b>	Not Available

**SECTION 10 STABILITY AND REACTIVITY**

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

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## Hazardous decomposition products

See section 5

## SECTION 11 TOXICOLOGICAL INFORMATION

## Information on toxicological effects

<b>Inhaled</b>	Not normally a hazard due to non-volatile nature of product The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.
<b>Ingestion</b>	The material has <b>NOT</b> 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.
<b>Skin Contact</b>	There is some evidence to suggest that this material can cause inflammation of the skin on contact in some persons. 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. Excessive use or prolonged contact may lead to defatting, drying and irritation of sensitive skin
<b>Eye</b>	There is some evidence to suggest that this material can cause eye irritation and damage in some persons.
<b>Chronic</b>	Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure. Some evidence exists that 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. Studies show that inhaling this substance for over a long period (e.g. in an occupational setting) may increase the risk of cancer.

	TOXICITY	IRRITATION
<b>Dentsply Regisil - Regisil 2X - Regisil PB - Regisil Rigid</b>	Oral (Rat) LD50: >2000 mg/kg <sup>[2]</sup>	Not Available
<b>dimethylsiloxane, vinyl-terminated</b>	Not Available	Not Available
<b>calcium sulfate</b>	Oral (rat) LD50: >1581 mg/kg <sup>[1]</sup>	Not Available
<b>silica amorphous</b>	Dermal (rabbit) LD50: >5000 mg/kg <sup>[2]</sup> Inhalation (rat) LC50: >0.139 mg/l/14h**[Grace] <sup>[2]</sup> Oral (rat) LD50: 3160 mg/kg <sup>[2]</sup>	Eye (rabbit): non-irritating * Skin (rabbit): non-irritating *
<b>crystalobalite</b>	Not Available	Not Available
<b>dimethylsiloxane, methylhydrogen-</b>	Not Available	Not Available
<b>silica amorphous, fumed</b>	Oral (rat) LD50: >5000 mg/kg <sup>[2]</sup>	Not Available
<b>titanium dioxide</b>	Inhalation (rat) LC50: >2.28 mg/l/4 h <sup>[1]</sup> Oral (rat) LD50: >2000 mg/kg <sup>[1]</sup>	Skin (human): 0.3 mg /3D (int)-mild *
<b>benzyl-C7-C8-alkyl phthalate</b>	Dermal (rabbit) LD50: >7940 mg/kg <sup>[2]</sup> Oral (rat) LD50: >15800 mg/kg <sup>[2]</sup>	Eye (rabbit): 0.0/110.0 * Skin (rabbit): 0.5/8.0 * mild
<b>ar-tosylamide/ formaldehyde/ melamine polymer</b>	Not Available	Not Available
<b>C.I. Pigment Violet 15</b>	Oral (rat) LD50: >10,000 mg/kg <sup>[2]</sup>	Animal tests have also demonstrated no skin irritation or sensitization. [IC]

**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

**CALCIUM SULFATE**

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

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	<p>severe bronchial hyperreactivity on methacholine challenge testing, and the lack of minimal lymphocytic inflammation, without eosinophilia. 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.</p> <p>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.</p> <p>Synergistic/antagonistic effects: Gypsum appears to be protective on quartz toxicity in animal testing.</p>
<b>SILICA AMORPHOUS</b>	<p>The substance is classified by IARC as Group 3: <b>NOT</b> classifiable as to its carcinogenicity to humans.</p> <p>Evidence of carcinogenicity may be inadequate or limited in animal testing.</p> <p>Reports indicate high/prolonged exposures to amorphous silicas induced lung fibrosis in experimental animals; in some experiments these effects were reversible. [PATTYS]</p>
<b>CRISTOBALITE</b>	<p><b>WARNING:</b> For inhalation exposure <u>ONLY</u>: This substance has been classified by the IARC as Group 1: <b>CARCINOGENIC TO HUMANS</b></p> <p>The International Agency for Research on Cancer (IARC) has classified occupational exposures to <b>respirable</b> (&lt;5 µm) 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.</p> <p>Inhalation (human) TCLo: 16 mppcf*8H/17.9y-1 * Millions of particles per cubic foot</p>
<b>SILICA AMORPHOUS, FUMED</b>	<p>For silane, dichloro-methyl-, reaction products with silica: Acute oral toxicity is very low for treated silica. Animals who inhaled these substances recovered from inflammatory changes in the airway when exposure ended. Repeated inhalation in animals caused inflammation and scarring of the lungs with enlarged lymph nodes. Treated silica does not cause mutations or genetic damage and has not been shown to cause cancer.</p>
<b>TITANIUM DIOXIDE</b>	<p>The material may produce moderate eye irritation leading to inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis. Exposure to titanium dioxide is via inhalation, swallowing or skin contact. When inhaled, it may deposit in lung tissue and lymph nodes causing dysfunction of the lungs and immune system. Absorption by the stomach and intestines depends on the size of the particle. It penetrated only the outermost layer of the skin, suggesting that healthy skin may be an effective barrier.</p> <p><b>WARNING:</b> This substance has been classified by the IARC as Group 2B: Possibly Carcinogenic to Humans.</p> <p>* IUCLID</p>
<b>BENZYL-C7-C8-ALKYL PHTHALATE</b>	<p>High Molecular Weight Phthalate Esters (HMWPEs) Category</p> <p>The HMWPE group includes chemically similar substances produced from alcohols. These substances have been demonstrated to have few biological effects. They demonstrate minimal acute toxicity, with effect on the liver and kidney at high doses. They also cause reproductive and developmental toxicity, also, liver cancer.</p> <p>The material may produce peroxisome proliferation. Peroxisomes are single, membrane limited organelles in the cytoplasm that are found in the cells of animals, plants, fungi, and protozoa.</p> <p>The material may be irritating to the eye, with prolonged contact causing inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.</p> <p>* Monsanto</p>
<b>DIMETHYLSILOXANE, VINYL-TERMINATED &amp; DIMETHYLSILOXANE, METHYLHYDROGEN-</b>	<p>Siloxanes may impair liver and hormonal function, as well as the lung and kidney. They have not been found to be irritating to the skin and eyes. They may potentially cause cancer (tumours of the womb in females) and may cause impaired fertility or infertility.</p>
<b>SILICA AMORPHOUS &amp; SILICA AMORPHOUS, FUMED</b>	<p>For silica amorphous:</p> <p>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.</p>
<b>DIMETHYLSILOXANE, METHYLHYDROGEN- &amp; AR-TOSYLAMIDE/ FORMALDEHYDE/ MELAMINE POLYMER</b>	<p>No significant acute toxicological data identified in literature search.</p>
<b>TITANIUM DIOXIDE &amp; BENZYL-C7-C8-ALKYL PHTHALATE</b>	<p>The material may cause skin irritation after prolonged or repeated exposure and may produce on contact skin redness, swelling, the production of vesicles, scaling and thickening of the skin.</p>

<b>Acute Toxicity</b>	✘	<b>Carcinogenicity</b>	✔
<b>Skin Irritation/Corrosion</b>	⊖	<b>Reproductivity</b>	⊖
<b>Serious Eye Damage/Irritation</b>	✔	<b>STOT - Single Exposure</b>	✔
<b>Respiratory or Skin sensitisation</b>	⊖	<b>STOT - Repeated Exposure</b>	⊖
<b>Mutagenicity</b>	⊖	<b>Aspiration Hazard</b>	⊖

**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 Regisil - Regisil 2X - Regisil PB - Regisil Rigid	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	Not Available	Not Available	Not Available	Not Available	Not Available

dimethylsiloxane, vinyl-terminated	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	Not Available	Not Available	Not Available	Not Available	Not Available

## Dentsply Regisil - Regisil 2X - Regisil PB - Regisil Rigid

	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
calcium sulfate	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
silica amorphous	LC50	96	Fish	ca.2000mg/L	1
	EC50	48	Crustacea	ca.7600mg/L	1
	EC50	72	Algae or other aquatic plants	440mg/L	1
	EC10	72	Algae or other aquatic plants	140mg/L	1
	NOEC	72	Algae or other aquatic plants	60mg/L	1
cristobalite	Not Available	Not Available	Not Available	Not Available	Not Available
	Not Available	Not Available	Not Available	Not Available	Not Available
dimethylsiloxane, methylhydrogen-	Not Available	Not Available	Not Available	Not Available	Not Available
	Not Available	Not Available	Not Available	Not Available	Not Available
silica amorphous, fumed	NOEC	24	Crustacea	>=10000mg/L	1
	NOEC	24	Crustacea	>=10000mg/L	1
titanium dioxide	LC50	96	Fish	155mg/L	2
	EC50	48	Crustacea	>10mg/L	2
	EC50	72	Algae or other aquatic plants	5.83mg/L	4
	EC20	72	Algae or other aquatic plants	1.81mg/L	4
	NOEC	336	Fish	0.089mg/L	4
benzyl-C7-C8-alkyl phthalate	EC50	48	Crustacea	=0.3mg/L	1
	EC50	96	Algae or other aquatic plants	=0.3mg/L	1
	NOEC	528	Crustacea	=0.039mg/L	1
ar-tosylamide/ formaldehyde/ melamine polymer	Not Available	Not Available	Not Available	Not Available	Not Available
	Not Available	Not Available	Not Available	Not Available	Not Available
C.I. Pigment Violet 15	Not Available	Not Available	Not Available	Not Available	Not Available
	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
silica amorphous	LOW	LOW
titanium dioxide	HIGH	HIGH

## Bioaccumulative potential

Ingredient	Bioaccumulation
calcium sulfate	LOW (LogKOW = -2.2002)
silica amorphous	LOW (LogKOW = 0.5294)
titanium dioxide	LOW (BCF = 10)

## Mobility in soil

Ingredient	Mobility

Continued...



## Dentsply Regisil - Regisil 2X - Regisil PB - Regisil Rigid

calcium sulfate	LOW (KOC = 6.124)
silica amorphous	LOW (KOC = 23.74)
titanium dioxide	LOW (KOC = 23.74)

## SECTION 13 DISPOSAL CONSIDERATIONS

## Waste treatment methods

Product / Packaging disposal	<ul style="list-style-type: none"> <li>▶ Consult manufacturer for recycling options and recycle where possible .</li> <li>▶ Consult State Land Waste Management Authority for disposal.</li> <li>▶ Incinerate residue at an approved site.</li> <li>▶ Recycle containers if possible, or dispose of in an authorised landfill.</li> <li>▶ Containers may still present a chemical hazard/ danger when empty.</li> <li>▶ Return to supplier for reuse/ recycling if possible.</li> </ul> <p>Otherwise:</p> <ul style="list-style-type: none"> <li>▶ If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorised landfill.</li> <li>▶ Where possible retain label warnings and SDS and observe all notices pertaining to the product.</li> </ul>
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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

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

## DIMETHYLSILOXANE, VINYL-TERMINATED(68083-19-2) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

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

Australia Exposure Standards

Australia Inventory of Chemical Substances (AICS)

## SILICA AMORPHOUS(7631-86-9) 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

## 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

## DIMETHYLSILOXANE, METHYLHYDROGEN-(68037-59-2) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

## SILICA AMORPHOUS, FUMED(68611-44-9) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Hazardous Substances Information System - Consolidated Lists

Australia Inventory of Chemical Substances (AICS)

## TITANIUM DIOXIDE(13463-67-7) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Exposure Standards

Australia Inventory of Chemical Substances (AICS)

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

## BENZYL-C7-C8-ALKYL PHTHALATE(68515-40-2) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

## AR-TOSYLAMIDE/ FORMALDEHYDE/ MELAMINE POLYMER(39277-28-6) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

## C.I. PIGMENT VIOLET 15(12769-96-9) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

National Inventory	Status
Australia - AICS	Y
Canada - DSL	Y

## Dentsply Regisil - Regisil 2X - Regisil PB - Regisil Rigid

Canada - NDSL	N (silica amorphous, fumed; dimethylsiloxane, vinyl-terminated; C.I. Pigment Violet 15; ar-tosylamide/ formaldehyde/ melamine polymer; cristobalite; dimethylsiloxane, methylhydrogen-; benzyl-C7-C8-alkyl phthalate; calcium sulfate)
China - IECSC	Y
Europe - EINEC / ELINCS / NLP	N (dimethylsiloxane, vinyl-terminated; ar-tosylamide/ formaldehyde/ melamine polymer; dimethylsiloxane, methylhydrogen-)
Japan - ENCS	N (silica amorphous, fumed; dimethylsiloxane, vinyl-terminated; C.I. Pigment Violet 15; dimethylsiloxane, methylhydrogen-; benzyl-C7-C8-alkyl phthalate)
Korea - KECI	Y
New Zealand - NZIoC	Y
Philippines - PICCS	Y
USA - TSCA	Y
<b>Legend:</b>	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 amorphous	7631-86-9, 112945-52-5, 67762-90-7, 68611-44-9, 68909-20-6, 112926-00-8, 61790-53-2, 60676-86-0, 91053-39-3, 69012-64-2, 844491-94-7
silica amorphous, fumed	68611-44-9, 112945-52-5, 60842-32-2
titanium dioxide	13463-67-7, 1317-70-0, 1317-80-2, 12188-41-9, 1309-63-3, 100292-32-8, 101239-53-6, 116788-85-3, 12000-59-8, 12701-76-7, 12767-65-6, 12789-63-8, 1344-29-2, 185323-71-1, 185828-91-5, 188357-76-8, 188357-79-1, 195740-11-5, 221548-98-7, 224963-00-2, 246178-32-5, 252962-41-7, 37230-92-5, 37230-94-7, 37230-95-8, 37230-96-9, 39320-58-6, 39360-64-0, 39379-02-7, 416845-43-7, 494848-07-6, 494848-23-6, 494851-77-3, 494851-98-8, 55068-84-3, 55068-85-4, 552316-51-5, 62338-64-1, 767341-00-4, 97929-50-5, 98084-96-9
C.I. Pigment Violet 15	12769-96-9, 12770-94-4, 1345-00-2, 12627-42-8

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

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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