

SAFETY DATA SHEETS

This SDS packet was issued with item:

071811900

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).

071811843 071811850 071811868 071811983 071813005 071813054 071813062

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

Dentsply (Australia)

Chemwatch: 4993-58

Version No: 4.1.1.1

Material Safety Data Sheet according to NOHSC and ADG requirements

Chemwatch Hazard Alert Code: 3

Issue Date: 01/01/2013

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Initial Date: Not Available

S.Local.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
Chemical Name	Not Applicable
Synonyms	Part number: 619100 - 619999, Regisil - Regisil 2X - Regisil PB - Regisil Rigid, Vinyl Polysiloxane Bite Registration Material
Proper shipping name	Not Applicable
Chemical formula	Not Applicable
Other means of identification	Not Available
CAS number	Not Applicable

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 manufacturer/importer

Registered company name	Dentsply (Australia)
Address	11-21 Gilby Road Mount Waverley 3149 VIC Australia
Telephone	+61 3 9538 8240
Fax	+61 3 9538 8260
Website	www.dentsply.com.au
Email	Not Available

Emergency telephone number

Association / Organisation	Not Available
Emergency telephone numbers	1300 552 929 (Mon-Fri 9am-5pm)
Other emergency telephone numbers	1300 552 929 (Mon-Fri 9am-5pm)

SECTION 2 HAZARDS IDENTIFICATION

Classification of the substance or mixture

HAZARDOUS SUBSTANCE. NON-DANGEROUS GOODS. According to the Criteria of NOHSC, 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
Risk Phrases ^[1]	R36/37 Irritating to eyes and respiratory system.
Legend:	1. Classified by Chemwatch; 2. Classification drawn from HSIS ; 3. Classification drawn from EC Directive 1272/2008 - Annex VI

Dentsply Regisil - Regisil 2X - Regisil PB -



Relevant risk statements are found in section 2

Indication(s) of danger	Xi
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SAFETY ADVICE

S25	Avoid contact with eyes.
S26	In case of contact with eyes, rinse with plenty of water and contact Doctor or Poisons Information Centre.
S39	Wear eye/face protection.
S40	To clean the floor and all objects contaminated by this material, use water and detergent.
S46	If swallowed, seek medical advice immediately and show this container or label.
S56	Dispose of this material and its container at hazardous or special waste collection point.
S64	If swallowed, rinse mouth with water (only if the person is conscious).

Other hazards

	May produce skin discomfort*.
	Cumulative effects may result following exposure*.
	Inhalation may produce health damage*.
	Limited evidence of a carcinogenic effect*.
	May possibly affect fertility*.

SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

Substances

See section below for composition of Mixtures

Mixtures

CAS No	%[weight]	Name
68083-19-2	30-60	dimethylsiloxane, vinyl-terminated
7778-18-9	5-30	calcium sulfate
7631-86-9	5-30	silica amorphous
14464-46-1	5-30	cristobalite
68037-59-2	5-15	dimethylsiloxane, methylhydrogen-
68611-44-9	<10	silica amorphous, fumed
13463-67-7	<5	titanium dioxide
68515-40-2	<5	benzyl-C7-C8-alkyl phthalate
Not Available	<5	organo platinum complex
39277-28-6	<2	ar-tosylamide/ formaldehyde/ melamine polymer
12769-96-9	<2	C.I. Pigment Violet 15

SECTION 4 FIRST AID MEASURES

Description of first aid measures

Eye Contact	If this product comes in contact with the eyes: ▶ Immediately hold eyelids apart and flush the eye continuously with 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. ▶ Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes. ▶ Transport to hospital or doctor without delay. ▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	If skin or hair contact occurs: ▶ Immediately flush body and clothes with large amounts of water, using safety shower if available. ▶ Quickly remove all contaminated clothing, including footwear.

Dentsply Regisil - Regisil 2X - Regisil PB -

	- Wash skin and hair with running water. Continue flushing with water until advised to stop by the Poisons Information Centre. - Transport to hospital, or doctor.
Inhalation	- If fumes, aerosols or combustion products are inhaled remove from contaminated area. - Other measures are usually unnecessary.
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**

	- Foam. - Dry chemical powder. - BCF (where regulations permit). - Carbon dioxide.
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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	- Alert Fire Brigade and tell them location and nature of hazard. - Wear breathing apparatus plus protective gloves. - Prevent, by any means available, spillage from entering drains or water courses. - Use water delivered as a fine spray to control fire and cool adjacent area.
Fire/Explosion Hazard	- High temperature decomposition products include silicon dioxide, small amounts of formaldehyde, formic acid, acetic acid and traces of silicon polymers. - These gases may ignite and, depending on circumstances, may cause the resin/polymer to ignite. - An outer skin of silica may also form. Extinguishing of fire, beneath the skin, may be difficult.

SECTION 6 ACCIDENTAL RELEASE MEASURES**Personal precautions, protective equipment and emergency procedures**

Minor Spills	Slippery when spilt. - Clean up all spills immediately. - Avoid breathing vapours and contact with skin and eyes. - Control personal contact with the substance, by using protective equipment.
Major Spills	Slippery when spilt. Minor hazard. - Clear area of personnel. - Alert Fire Brigade and tell them location and nature of hazard.
Personal Protective Equipment advice is contained in Section 8 of the MSDS.	

SECTION 7 HANDLING AND STORAGE**Precautions for safe handling**

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.
Other information	- Store in original containers. - Keep containers securely sealed. - Store in a cool, dry, well-ventilated area. - Store away from incompatible materials and foodstuff containers.

Conditions for safe storage, including any incompatibilities

Suitable container	- Polyethylene or polypropylene container. - Packing as recommended by manufacturer. - Check all containers are clearly labelled and free from leaks.
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**Storage
incompatibility**

► Avoid reaction with oxidising agents

PACKAGE MATERIAL INCOMPATIBILITIES

Not Available

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	calcium sulfate	Calcium sulphate (a)	10 mg/m3	Not Available	Not Available	Not Available
Australia Exposure Standards	silica amorphous	Silica - Amorphous Fumed silica (respirable dust) / Fumed silica (respirable dust)	2 mg/m3	Not Available	Not Available	Not Available
Australia Exposure Standards	cristobalite	Silica - Crystalline Cristobalite (respirable dust) / Cristobalite (respirable dust)	0.1 mg/m3	Not Available	Not Available	Not Available
Australia Exposure Standards	titanium dioxide	Titanium dioxide (a)	10 mg/m3	Not Available	Not Available	Not Available

EMERGENCY LIMITS

Ingredient	TEEL-0	TEEL-1	TEEL-2	TEEL-3
Dentsply Regisil - Regisil 2X - Regisil PB - Regisil Rigid	Not Available	Not Available	Not Available	Not Available

Ingredient	Original IDLH	Revised IDLH
dimethylsiloxane, vinyl-terminated	Not Available	Not Available
calcium sulfate	Not Available	Not Available
silica amorphous	N.E. mg/m3 / N.E. ppm	3,000 mg/m3
cristobalite	N.E. mg/m3 / N.E. ppm	25 mg/m3
dimethylsiloxane, methylhydrogen-	Not Available	Not Available
silica amorphous, fumed	N.E. mg/m3 / N.E. ppm	3,000 mg/m3
titanium dioxide	N.E. mg/m3 / N.E. ppm	5,000 mg/m3
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.
Personal protection	

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Eye and face protection	- Chemical goggles. - Full face shield may be required for supplementary but never for primary protection of eyes. - 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.
Skin protection	See Hand protection below
Hands/feet protection	Wear protective gloves, e.g. PVC. - Wear chemical protective gloves, e.g. PVC. - Wear safety footwear or safety gumboots, e.g. Rubber
Body protection	See Other protection below
Other protection	- Overalls. - P.V.C. apron. - Barrier cream.
Thermal hazards	Not Available

Recommended material(s)

GLOVE SELECTION INDEX

Glove selection is based on a modified presentation of the:

"Forsberg Clothing Performance Index".

The effect(s) of the following substance(s) are taken into account in the **computer-generated** selection:

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Material	CPI
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* CPI - Chemwatch Performance Index

A: Best Selection

B: Satisfactory; may degrade after 4 hours continuous immersion

C: Poor to Dangerous Choice for other than short term immersion

NOTE: As a series of factors will influence the actual performance of the glove, a final selection must be based on detailed observation. -

* Where the glove is to be used on a short term, casual or infrequent basis, factors such as "feel" or convenience (e.g. disposability), may dictate a choice of gloves which might otherwise be unsuitable following long-term or frequent use. A qualified practitioner should be consulted.

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(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)

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

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

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Lower Explosive Limit (%)	Not Available	Volatile Component (%vol)	Not Available
Vapour pressure (kPa)	Not Applicable	Gas group	Not Available
Solubility in water (g/L)	Immiscible	pH as a solution(1%)	Not Available
Vapour density (Air = 1)	Not Applicable	VOC g/L	Not Available

SECTION 10 STABILITY AND REACTIVITY

Reactivity	See section 7
Chemical stability	- Unstable in the presence of incompatible materials. - Product is considered stable. - Hazardous polymerisation will not occur. - Presence of elevated temperatures.
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	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.
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. The material may still be damaging to the health of the individual, following ingestion, especially where pre-existing organ (e.g liver, kidney) damage is evident. Present definitions of harmful or toxic substances are generally based on doses producing mortality rather than those producing morbidity (disease, ill-health).
Skin Contact	Limited evidence exists, or practical experience predicts, that the material either produces inflammation of the skin in a substantial number of individuals following direct contact, and/or produces significant inflammation when applied to the healthy intact skin of animals, for up to four hours, such inflammation being present twenty-four hours or more after the end of the exposure period. Skin irritation may also be present after prolonged or repeated exposure; this may result in a form of contact dermatitis (nonallergic). The dermatitis is often characterised by skin redness (erythema) and swelling (oedema) which may progress to blistering (vesiculation), scaling and thickening of the epidermis. At the microscopic level there may be intercellular oedema of the spongy layer of the skin (spongiosis) and intracellular oedema of the epidermis.
Eye	Limited evidence exists, or practical experience suggests, that the material may cause eye irritation in a substantial number of individuals and/or is expected to produce significant ocular lesions which are present twenty-four hours or more after instillation into the eye(s) of experimental animals. Repeated or prolonged eye contact may cause inflammation characterised by temporary redness (similar to windburn) of the conjunctiva (conjunctivitis); temporary impairment of vision and/or other transient eye damage/ulceration may occur.
Chronic	Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems. There is limited evidence that the material may produce serious damage (clear functional disturbance or morphological change which may have toxicological significance) following repeated or prolonged exposure. As a rule the material may produce, or contains a substance which may produce severe lesions. Such damage may become apparent following direct application in subchronic (90 day) toxicity studies or following sub-acute (28 day) or chronic (two-year) toxicity tests.

Dentsply Regisil - Regisil 2X - Regisil PB - Regisil Rigid	TOXICITY	IRRITATION
	Oral (Rat) LD50: >2000 mg/kg	Not Available
dimethylsiloxane, vinyl-terminated	TOXICITY	IRRITATION
	Dermal (rabbit) LD50: >16 ml/kg	
	Oral (rat) LD50: >16 ml/kg	

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	Not Available	Not Available
calcium sulfate	TOXICITY	IRRITATION
	Not Available	Not Available
silica amorphous	TOXICITY	IRRITATION
	Dermal (rabbit) LD50: >5000 mg/kg *	* [Grace]
	Inhalation (rat) LC50: >0.139 mg/l/14h *	Eye (rabbit): non-irritating *
	Oral (rat) LD50: 3160 mg/kg	Skin (rabbit): non-irritating *
	Not Available	Not Available
cristobalite	TOXICITY	IRRITATION
	Not Available	Not Available
dimethylsiloxane, methylhydrogen-	TOXICITY	IRRITATION
	Not Available	Not Available
silica amorphous, fumed	TOXICITY	IRRITATION
	Oral (rat) LD50: >5000 mg/kg	[Wacker]
	Not Available	Not Available
titanium dioxide	TOXICITY	IRRITATION
	Oral (Mouse) LD50: >10000 mg/kg *	Skin (human): 0.3 mg /3D (int)-mild *
	Oral (Rat) LD50: >20000 mg/kg *	
	Not Available	Not Available
benzyl-C7-C8-alkyl phthalate	TOXICITY	IRRITATION
	Dermal (Rabbit) LD50: >7940 * mg/kg	Eye (rabbit): 0.0/110.0 *
	Oral (rat) LD50: >15800 mg/kg *	Skin (rabbit): 0.5/8.0 * mild
	Not Available	Not Available
ar-tosylamide/ formaldehyde/ melamine polymer	TOXICITY	IRRITATION
	Not Available	Not Available
C.I. Pigment Violet 15	TOXICITY	IRRITATION
	Oral (rat) LD50: >10,000 mg/kg	
	Not Available	Not Available

* Value obtained from manufacturer's msds

unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances

CALCIUM SULFATE	Asthma-like symptoms may continue for months or even years after exposure to the material ceases. This may be due to a non-allergenic condition known as reactive airways dysfunction syndrome (RADS) which can occur following exposure to high levels of highly irritating compound. Key criteria for the diagnosis of RADS include the absence of preceding respiratory disease, in a non-atopic individual, with abrupt onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. A reversible airflow pattern, on spirometry, with the presence of moderate to severe bronchial hyperreactivity on methacholine challenge testing and the lack of minimal lymphocytic inflammation, without eosinophilia, have also been included in the criteria for diagnosis of RADS.
SILICA AMORPHOUS	Reports indicate high/prolonged exposures to amorphous silicas induced lung fibrosis in experimental animals; in some experiments these effects were reversible. [PATYYS]

Dentsply Regisil - Regisil 2X - Regisil PB -

CRISTOBALITE	WARNING: For inhalation exposure <u>ONLY</u>: This substance has been classified by the IARC as Group 1: CARCINOGENIC TO HUMANS The International Agency for Research on Cancer (IARC) has classified occupational exposures to respirable (<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. Inhalation (human) TClO: 16 mppcf*/8H/17.9y-I * Millions of particles per cubic foot
TITANIUM DIOXIDE	The material may produce moderate eye irritation leading to inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis. The material may cause skin irritation after prolonged or repeated exposure and may produce a contact dermatitis (nonallergic). This form of dermatitis is often characterised by skin redness (erythema) and swelling epidermis. * IUCLID
BENZYL-C7-C8-ALKYL PHTHALATE	The material may produce peroxisome proliferation. Peroxisomes are single, membrane limited, cytoplasmic organelles that are found in the cells of animals, plants, fungi and protozoa. Peroxisome proliferators include certain hypolipidaemic drugs, phthalate ester plasticisers, industrial solvents, herbicides, food flavours, leukotriene D4 antagonists and hormones. Numerous studies in rats and mice have demonstrated the hepatocarcinogenic effects of peroxisome proliferators, and these compounds have been unequivocally established as carcinogens. * Monsanto
AR-TOSYLAMIDE/ FORMALDEHYDE/ MELAMINE POLYMER	No significant acute toxicological data identified in literature search.
C.I. PIGMENT VIOLET 15	NOTE: 90 day (chronic), teratological and mutagenicity tests have all provided negative results. Animal tests have also demonstrated no skin irritation or sensitization. [ICI]
DIMETHYLSILOXANE, VINYL-TERMINATED, DIMETHYLSILOXANE, METHYLHYDROGEN-	For siloxanes: Effects which based on the reviewed literature do not seem to be problematic are acute toxicity, irritant effects, sensitization and genotoxicity. Some studies indicate that some of the siloxanes may have endocrine disrupting properties, and reproductive effects have caused concern about the possible effects of the siloxanes on humans and the environment. Only few siloxanes are described in the literature with regard to health effects, and it is therefore not possible to make broad conclusions and comparisons of the toxicity related to short-chained linear and cyclic siloxanes based on the present evaluation. Data are primarily found on the cyclic siloxanes D4 (octamethylcyclotetrasiloxane) and D5 (decamethylcyclopentasiloxane) and the short-linear HMDS (hexamethyldisiloxane).
SILICA AMORPHOUS, SILICA AMORPHOUS, FUMED	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.

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 required to make classification available
 ✗ – Data available but does not fill the criteria for classification
 ☹ – Data Not Available to make classification

CMR STATUS

Not Applicable

SECTION 12 ECOLOGICAL INFORMATION**Toxicity****DO NOT** discharge into sewer or waterways.**Persistence and degradability**

Dentsply Regisil - Regisil 2X - Regisil PB -

Ingredient	Persistence: Water/Soil	Persistence: Air
calcium sulfate	LOW	LOW
silica amorphous	HIGH	HIGH
titanium dioxide	LOW	LOW

Bioaccumulative potential

Ingredient	Bioaccumulation
calcium sulfate	LOW (BCF = 3.162)
silica amorphous	LOW (BCF = 3.162)
titanium dioxide	LOW (BCF = 10)

Mobility in soil

Ingredient	Mobility
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	- Consult manufacturer for recycling options and recycle where possible . - Consult State Land Waste Management Authority for disposal. - Incinerate residue at an approved site. - Recycle containers if possible, or dispose of in an authorised landfill.
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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 73 / 78 and the IBC code

Source	Ingredient	Pollution Category
IMO MARPOL 73/78 (Annex II) - List of Noxious Liquid Substances Carried in Bulk	titanium dioxide	Z

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

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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 Inventory of Chemical Substances (AICS)", "Australia Hazardous Substances Information System - Consolidated Lists"
titanium dioxide(13463-67-7) is found on the following regulatory lists	"Australia Exposure Standards", "International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs", "Australia Inventory of Chemical Substances (AICS)"
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)"

SECTION 16 OTHER INFORMATION

Other information

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.

A list of reference resources used to assist the committee may be found at:

www.chemwatch.net/references

The (M)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.

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DENTSPLY Milford

Safety Data Sheet

519899

1. Identification

Product Name Regisil® Bite Registration Material	SDS Code Number 519899
Substance Identity Regisil® Vinyl Polysiloxane Bite Registration Material	Date of Last Revision 11/04/16
Manufacturer: DENTSPLY Milford	Address 38 West Clarke Avenue Milford DE 19963-1805 http://www.dentsply.com
Grades or Minor Variant Identities Regisil, Regisil 2X, Regisil PB, Regisil Rigid	Information Telephone Number (302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)
Product Use (for Canada) Dental Bite Registration 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	14464-46-1	0.05 mg/m ³	< than 55
Silicon Dioxide - Amorphous	7631-86-9	1.2 mg/m ³	< than 35
Calcium Sulfate	7778-18-9	10 mg/m ³	< than 15
Hydrophobic Amorphous Fumed Silica	68611-44-9	10 mg/m ³	< than 10
Titanium Dioxide	13463-67-7	10 mg/m ³	< than 5

Colorant Information The base pastes may contain fluorescent organic dyes and/or ultramarine pigments. The Chemical structure of all Ultramarine pigments, regardless of color, is Sodium Aluminosulfosilicate.

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 paste and as such will not flow.		
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 contact dermatitis to susceptible persons. Ensure adequate ventilation.		
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 away from food and beverages.

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	Not Required	Not Applicable
Body Protection	Protective work clothing	Not Applicable
Occupational Exposure Limits: Not Applicable		Engineering Controls: Not Applicable

9. Physical and Chemical Characteristics

Appearance: Various colored pastes, may be high viscosity paste or runny. Catalyst is grey-colored.	Odor: Characteristic sweet ester odor.	
Normal Physical State: Material is available in several viscosities. It varies from a very high viscosity liquid (Paste) to a more runny material.	Melting Point: Not Applicable	
Specific Gravity: 1.2 g/cm ³ (1.6 g/cm ³ for PB & Rigid)	Solubility in Water: Not soluble	pH: Not Applicable
Vapor Pressure (mm Hg): Not Applicable	Vapor Density (AIR=1): Not Applicable	Evaporation Rate (Butyl Acetate =1): N A
Flashpoint Method: Not Applicable	Flammable (Explosive) Limits in Air LEL: Not Applicable UEL: Not Applicable	Autoignition Temperature: Not Applicable, Product will not autoignite.
Other: Not Applicable		

10. Stability and Reactivity Data

Incompatibility (Materials to Avoid): Strong oxidizing materials.		
Hazardous Products Produced During Decomposition: No dangerous decomposition products known if used according to Directions for Use.		
Hazardous Polymerization: ☐ May Occur ☒ May Not Occur	Conditions to Avoid: None known	
Stability? ☒ Stable ☐ 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 and mucous membranes. The unpolymerized product may cause irritation to the skin in susceptible persons. 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 an irritant	Single & Repeated	Moderate	Irritation or possible allergic response.	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 = 1, 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: Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
 Dispose of material as solid waste in a closed container. Dispose of in accordance with Federal, State and Local regulations
 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> : 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.