# Dentsply Reprosil Impression Material

**Dentsply Sirona Pty Ltd**

Chemwatch Hazard Alert Code: **3**

Chemwatch: **4993-59**
Version No: **5.1.1.1**
Safety Data Sheet according to WHS and ADG requirements

Issue Date: **27/06/2017**
Print Date: **10/01/2018**
S.GHS.AUS.EN

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

### Product Identifier

| | |
|---|---|
| **Product name** | Dentsply Reprosil Impression Material |
| **Synonyms** | Reprosil Vinyl Polysiloxane Impression Material. |
| **Other means of identification** | Not Available |

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

| | |
|---|---|
| **Relevant identified uses** | Dental bite registration 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 | 0 | |
| Toxicity | 2 | |
| Body Contact | 2 | |
| Reactivity | 1 | |
| Chronic | 3 | |

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

| | |
|---|---|
| **Poisons Schedule** | Not Applicable |
| **Classification [1]** | Skin Corrosion/Irritation Category 2, Eye Irritation Category 2A, Carcinogenicity Category 1A, 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)

| | |
|---|---|
| **H315** | Causes skin irritation. |
| **H319** | Causes serious eye irritation. |
| **H350** | May cause cancer. |
| **H373** | May cause damage to organs through prolonged or repeated exposure. |

### Precautionary statement(s) Prevention

**Continued...**

| | |
|---|---|
| **P201** | Obtain special instructions before use. |
| **P260** | Do not breathe dust/fume/gas/mist/vapours/spray. |
| **P281** | Use personal protective equipment as required. |
| **P280** | Wear protective gloves/protective clothing/eye protection/face protection. |

### Precautionary statement(s) Response

| | |
|---|---|
| **P308+P313** | IF exposed or concerned: Get medical advice/attention. |
| **P362** | Take off contaminated clothing and wash before reuse. |
| **P305+P351+P338** | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |
| **P314** | Get medical advice/attention if you feel unwell. |

### Precautionary statement(s) Storage

| | |
|---|---|
| **P405** | Store locked up. |

### 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 |
|---|---|---|
| 7631-86-9 | <30 | silica amorphous |
| 14464-46-1 | <30 | cristobalite |
| 7778-18-9 | <15 | calcium sulfate |
| 68909-20-6 | <10 | silica amorphous, fumed, hydrophobic |
| 13463-67-7 | <5 | titanium dioxide |
| | | may contain dyes and pigments: |
| Not Available | NotSpec. | fluorescent organic dyes |
| Not Available | NotSpec. | ultramarine pigments: |

## SECTION 4 FIRST AID MEASURES

### Description of first aid measures

| | |
|---|---|
| **Eye Contact** | If this product comes in contact with the eyes:<br>▸ Wash out immediately with fresh running water.<br>▸ 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.<br>▸ Seek medical attention without delay; if pain persists or recurs seek medical attention.<br>▸ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel. |
| **Skin Contact** | If skin contact occurs:<br>▸ Immediately remove all contaminated clothing, including footwear.<br>▸ Flush skin and hair with running water (and soap if available).<br>▸ Seek medical attention in event of irritation. |
| **Inhalation** | ▸ If fumes or combustion products are inhaled remove from contaminated area.<br>▸ Lay patient down. Keep warm and rested.<br>▸ Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures.<br>▸ 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.<br>▸ Transport to hospital, or doctor. |
| **Ingestion** | ▸ Immediately give a glass of water.<br>▸ 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

- Water spray or fog.
- Foam.
- Dry chemical powder.
- BCF (where regulations permit).

### 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 |

**Continued...**

### Advice 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.<br>▸ When heated to extreme temperatures, (>1700 deg.C) amorphous silica can fuse.<br>▸ Alert Fire Brigade and tell them location and nature of hazard.<br>▸ Wear breathing apparatus plus protective gloves in the event of a fire.<br>▸ Prevent, by any means available, spillage from entering drains or water courses.<br>▸ Use fire fighting procedures suitable for surrounding area. |
| **Fire/Explosion Hazard** | ▸ Non combustible.<br>▸ Not considered a significant fire risk, however containers may burn.<br>Combustion products include:<br>,<br>sulfur oxides (SOx)<br>,<br>silicon dioxide (SiO2)<br>,<br>metal oxides<br>,<br>other pyrolysis products typical of burning organic material.<br>May emit poisonous fumes.<br>May emit corrosive fumes. |
| **HAZCHEM** | Not Applicable |

## SECTION 6 ACCIDENTAL RELEASE MEASURES

### Personal precautions, protective equipment and emergency procedures

See section 8

### Environmental precautions

See section 12

### Methods and material for containment and cleaning up

| | |
|---|---|
| **Minor Spills** | ▸ Clean up all spills immediately.<br>▸ Avoid contact with skin and eyes.<br>▸ Wear impervious gloves and safety goggles.<br>▸ Trowel up/scrape up. |
| **Major Spills** | ▸ Clear area of personnel and move upwind.<br>▸ Alert Fire Brigade and tell them location and nature of hazard.<br>▸ Wear breathing apparatus plus protective gloves.<br>▸ Prevent, by any means available, spillage from entering drains or water course. |

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

## SECTION 7 HANDLING AND STORAGE

### Precautions for safe handling

| | |
|---|---|
| **Safe handling** | ▸ Avoid all personal contact, including inhalation.<br>▸ Wear protective clothing when risk of exposure occurs.<br>▸ Use in a well-ventilated area.<br>▸ Prevent concentration in hollows and sumps. |
| **Other information** | ▸ Store in original containers.<br>▸ Keep containers securely sealed.<br>▸ Store in a cool, dry, well-ventilated area.<br>▸ Store away from incompatible materials and foodstuff containers. |

### Conditions for safe storage, including any incompatibilities

| | |
|---|---|
| **Suitable container** | ▸ Polyethylene or polypropylene container.<br>▸ Packing as recommended by manufacturer.<br>▸ Check all containers are clearly labelled and free from leaks. |
| **Storage incompatibility** | ▸ Avoid reaction with oxidising agents |

## SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

### Control parameters

**OCCUPATIONAL EXPOSURE LIMITS (OEL)**

**INGREDIENT DATA**

| Source | Ingredient | Material name | TWA | STEL | Peak | Notes |
|---|---|---|---|---|---|---|
| Australia Exposure Standards | 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 | Silica gel | 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 | Diatomaceous earth (uncalcined) | 10 mg/m3 | Not Available | Not Available | Not Available |

**Continued...**

| | | | | | | |
|---|---|---|---|---|---|---|
| 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 | 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 | titanium dioxide | Titanium dioxide | 10 mg/m3 | Not Available | Not Available | Not Available |

**EMERGENCY LIMITS**

| Ingredient | Material name | TEEL-1 | TEEL-2 | TEEL-3 |
|---|---|---|---|---|
| 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 |
| 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 |
| titanium dioxide | Titanium oxide; (Titanium dioxide) | 30 mg/m3 | 330 mg/m3 | 2,000 mg/m3 |

| Ingredient | Original IDLH | Revised IDLH |
|---|---|---|
| silica amorphous | 3000 mg/m3 | Not Available |
| cristobalite | 25 mg/m3 | Not Available |
| calcium sulfate | Not Available | Not Available |
| silica amorphous, fumed, hydrophobic | Not Available | Not Available |
| titanium dioxide | 5000 mg/m3 | Not Available |
| fluorescent organic dyes | Not Available | Not Available |
| ultramarine pigments: | 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.<br>The basic types of engineering controls are:<br>Process controls which involve changing the way a job activity or process is done to reduce the risk.<br>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** |  |
| **Eye and face protection** | ▸ Safety glasses with side shields.<br>▸ Chemical goggles.<br>▸ 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 chemical protective gloves, e.g. PVC.<br>▸ Wear safety footwear or safety gumboots, e.g. Rubber<br>**NOTE:**<br>▸ The material may produce skin sensitisation in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact.<br>▸ Contaminated leather items, such as shoes, belts and watch-bands should be removed and destroyed. |
| **Body protection** | See Other protection below |
| **Other protection** | ▸ Overalls.<br>▸ P.V.C. apron.<br>▸ Barrier cream. |
| **Thermal hazards** | Not Available |

## Respiratory protection

If inhalation risk above the TLV exists, wear approved dust respirator.
Use respirators with protection factors appropriate for the exposure level.

**Continued...**

- 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

Cartridge respirators should never be used for emergency ingress or in areas of unknown vapour concentrations or oxygen content. The wearer must be warned to leave the contaminated area immediately on detecting any odours through the respirator. The odour may indicate that the mask is not functioning properly, that the vapour concentration is too high, or that the mask is not properly fitted. Because of these limitations, only restricted use of cartridge respirators is considered appropriate.

## SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

### Information on basic physical and chemical properties

| | |
|---|---|
| **Appearance** | Various coloured pastes with a characteristic sweet ester odour; does not mix with water. |

| | | | |
|---|---|---|---|
| **Physical state** | Non Slump Paste | **Relative density (Water = 1)** | 1.2-1.5 |
| **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)** | Not Available | **Molecular weight (g/mol)** | Not Applicable |
| **Flash point (°C)** | Not Applicable | **Taste** | Not Available |
| **Evaporation rate** | Not Available | **Explosive properties** | Not Available |
| **Flammability** | Not Applicable | **Oxidising properties** | Not Available |
| **Upper Explosive Limit (%)** | Not Applicable | **Surface Tension (dyn/cm or mN/m)** | Not Available |
| **Lower Explosive Limit (%)** | Not Applicable | **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.<br>▸ Product is considered stable.<br>▸ Hazardous polymerisation will not occur. |
| **Possibility of hazardous reactions** | See section 7 |
| **Conditions to avoid** | See section 7 |
| **Incompatible materials** | See section 7 |
| **Hazardous decomposition products** | See section 5 |

## SECTION 11 TOXICOLOGICAL INFORMATION

### Information on toxicological effects

| | |
|---|---|
| **Inhaled** | Inhalation of vapours or aerosols (mists, fumes), generated by the material during the course of normal handling, may be damaging to the health of the individual.<br>Effects on lungs are significantly enhanced in the presence of respirable particles.<br>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. |
| **Skin Contact** | This material can cause inflammation of the skin on contact in some persons.<br>The material may accentuate any pre-existing dermatitis condition<br>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.<br>Beta-hemihydrate (normal Plaster of Paris) does not cause skin burns in similar circumstances.<br>Open cuts, abraded or irritated skin should not be exposed to this material<br>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.<br>Excessive use or prolonged contact may lead to defatting, drying and irritation of sensitive skin |
| **Eye** | This material can cause eye irritation and damage in some persons. |
| **Chronic** | Harmful: danger of serious damage to health by prolonged exposure through inhalation.<br>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.<br>Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure.<br>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. |

**Continued...**

| | |
|---|---|
| | There has been concern that this material can cause cancer or mutations, but there is not enough data to make an assessment.<br>Amorphous silicas generally are less hazardous than crystalline silicas, but the former can be converted to the latter on heating and subsequent cooling.<br>Inhalation of dusts containing crystalline silicas may lead to silicosis, a disabling lung disease that may take years to develop. |

| | TOXICITY | IRRITATION |
|---|---|---|
| **Dentsply Reprosil Impression Material** | Oral (Rat) LD50: >2000 mg/kg[2] | Not Available |
| **silica amorphous** | **TOXICITY** | **IRRITATION** |
| | Dermal (rabbit) LD50: >5000 mg/kg[2] | Eye (rabbit): non-irritating * |
| | Inhalation (rat) LC50: >0.139 mg/l/14h**[Grace][2] | Skin (rabbit): non-irritating * |
| | Oral (rat) LD50: 3160 mg/kg[2] | |
| **cristobalite** | **TOXICITY** | **IRRITATION** |
| | Not Available | Not Available |
| **calcium sulfate** | **TOXICITY** | **IRRITATION** |
| | Oral (rat) LD50: >1581 mg/kg[1] | Not Available |
| **silica amorphous, fumed, hydrophobic** | **TOXICITY** | **IRRITATION** |
| | Oral (rat) LD50: >5000 mg/kg[2] | Eye (rabbit): none |
| | | Skin (rabbit): none [Degussa] |
| **titanium dioxide** | **TOXICITY** | **IRRITATION** |
| | Inhalation (rat) LC50: >2.28 mg/l4 h[1] | Skin (human): 0.3 mg /3D (int)-mild * |
| | Oral (rat) LD50: >2000 mg/kg[1] | |

| | |
|---|---|
| ***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* |

| | |
|---|---|
| **Dentsply Reprosil Impression Material** | The following information refers to contact allergens as a group and may not be specific to this product.<br>Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's oedema. The pathogenesis of contact eczema involves a cell-mediated (T lymphocytes) immune reaction of the delayed type. Other allergic skin reactions, e.g. contact urticaria, involve antibody-mediated immune reactions. |
| **SILICA AMORPHOUS** | The substance is classified by IARC as Group 3:<br>**NOT** classifiable as to its carcinogenicity to humans.<br>Evidence of carcinogenicity may be inadequate or limited in animal testing.<br>Reports indicate high/prolonged exposures to amorphous silicas induced lung fibrosis in experimental animals; in some experiments these effects were reversible. [PATTYS] |
| **CRISTOBALITE** | **WARNING:** For inhalation exposure ONLY: This substance has been classified by the IARC as Group 1: **CARCINOGENIC TO HUMANS**<br><br>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.<br>Inhalation (human) TCLo: 16 mppcf*/8H/17.9y-I * Millions of particles per cubic foot |
| **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 severe bronchial hyperreactivity on methacholine challenge testing, and the lack of minimal lymphocytic inflammation, without eosinophilia.<br>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.<br>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.<br>Synergistic/antagonistic effects: Gypsum appears to be protective on quartz toxicity in animal testing. |
| **TITANIUM DIOXIDE** | The material may produce moderate eye irritation leading to inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.<br>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.<br>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.<br><br>**WARNING:** This substance has been classified by the IARC as Group 2B: Possibly Carcinogenic to Humans.<br>* IUCLID |
| **Dentsply Reprosil Impression Material & SILICA AMORPHOUS & SILICA AMORPHOUS, FUMED, HYDROPHOBIC** | For silica amorphous:<br>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** | ⊘ |

**Continued...**

| | | | |
|---|---|---|---|
| **Serious Eye Damage/Irritation** | ✔ | **STOT - Single Exposure** | ⊘ |
| **Respiratory or Skin sensitisation** | ⊘ | **STOT - Repeated Exposure** | ✔ |
| **Mutagenicity** | ⊘ | **Aspiration Hazard** | ⊘ |

***Legend:*** ✘ *– Data available but does not fill the criteria for classification*
✔ *– Data available to make classification*
⊘ *– Data Not Available to make classification*

## SECTION 12 ECOLOGICAL INFORMATION

### Toxicity

**Dentsply Reprosil Impression Material**

| ENDPOINT | TEST DURATION (HR) | SPECIES | VALUE | SOURCE |
|---|---|---|---|---|
| Not Available | Not Available | Not Available | Not Available | Not Available |

**silica amorphous**

| ENDPOINT | TEST DURATION (HR) | SPECIES | VALUE | SOURCE |
|---|---|---|---|---|
| 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**

| ENDPOINT | TEST DURATION (HR) | SPECIES | VALUE | SOURCE |
|---|---|---|---|---|
| Not Available | Not Available | Not Available | Not Available | Not Available |

**calcium sulfate**

| ENDPOINT | TEST DURATION (HR) | SPECIES | VALUE | SOURCE |
|---|---|---|---|---|
| LC50 | 96 | Fish | >1970mg/L | 4 |
| EC50 | 96 | Algae or other aquatic plants | 3200mg/L | 4 |
| EC0 | 96 | Crustacea | =1255.000mg/L | 1 |
| NOEC | 504 | Crustacea | 360mg/L | 4 |

**silica amorphous, fumed, hydrophobic**

| ENDPOINT | TEST DURATION (HR) | SPECIES | VALUE | SOURCE |
|---|---|---|---|---|
| Not Available | Not Available | Not Available | Not Available | Not Available |

**titanium dioxide**

| ENDPOINT | TEST DURATION (HR) | SPECIES | VALUE | SOURCE |
|---|---|---|---|---|
| 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 |

***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 |
|---|---|---|
| silica amorphous | LOW | LOW |
| calcium sulfate | HIGH | HIGH |
| titanium dioxide | HIGH | HIGH |

### Bioaccumulative potential

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

### Mobility in soil

| Ingredient | Mobility |
|---|---|
| silica amorphous | LOW (KOC = 23.74) |

**Continued...**

| | |
|---|---|
| calcium sulfate | LOW (KOC = 6.124) |
| titanium dioxide | LOW (KOC = 23.74) |

## SECTION 13 DISPOSAL CONSIDERATIONS

### Waste treatment methods

| | |
|---|---|
| **Product / Packaging disposal** | ▸ Recycle wherever possible or consult manufacturer for recycling options.<br>▸ Consult State Land Waste Authority for disposal.<br>▸ Bury or incinerate residue at an approved site.<br>▸ Recycle containers if possible, or dispose of in an authorised landfill. |

## 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

**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

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

Australia Exposure Standards
Australia Inventory of Chemical Substances (AICS)

**SILICA AMORPHOUS, FUMED, HYDROPHOBIC(68909-20-6) IS FOUND ON THE FOLLOWING REGULATORY 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

| National Inventory | Status |
|---|---|
| Australia - AICS | Y |
| Canada - DSL | Y |
| Canada - NDSL | N (silica amorphous, fumed, hydrophobic; cristobalite; calcium sulfate) |
| China - IECSC | Y |
| Europe - EINEC / ELINCS / NLP | Y |
| Japan - ENCS | N (silica amorphous, fumed, hydrophobic) |
| Korea - KECI | Y |
| New Zealand - NZIoC | Y |
| Philippines - PICCS | Y |
| USA - TSCA | Y |
| ***Legend:*** | *Y = All ingredients are on the inventory*<br>*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 |
|---|---|

**Continued...**

| | |
|---|---|
| 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 |
| calcium sulfate | 7778-18-9, 10101-41-4, 14798-04-0 |
| 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 |

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