



Safety Data Sheet

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Document group:	05-6398-1	Version number:	8.00
Issue Date:	02/06/2025	Supersedes date:	16/01/2022

This Safety Data Sheet has been prepared in accordance with the Preparation of Safety Data Sheets for Hazardous Chemicals Code of Practice (Safe Work Australia, December 2011)

SECTION 1: Identification

1.1. Product identifier

Vitremer™ Core Buildup/Restorative Powder (3303)

Product Identification Numbers

70-2010-2396-0

1.2. Recommended use and restrictions on use

Recommended use

Dental Product, Glass Ionomer Restorative

Restrictions on use

For use by dental professionals only.

1.3. Supplier's details

Address:	KCI Medical Australia Pty Ltd, Level 3, Building A, 1 Rivett Rd North Ryde, NSW 2113
Telephone:	1800945183
E Mail:	psops_supportteam@solventum.com
Website:	Solventum.com

1.4. Emergency telephone number

+61 2 9037 2994; (24/7) +1-703-527-3887; (24/7)

SECTION 2: Hazard identification

This product is NOT classified as a hazardous chemical according to the Model Work Health and Safety Regulations, 2011, in accordance with applicable State and Territory legislation.

Refer to Section 14 of this Safety Data Sheets for product Dangerous Goods Classification.

2.1. Classification of the substance or mixture

Not applicable.

2.2. Label elements

Signal word

Not applicable.

Symbols

Not applicable.

Pictograms

Not applicable

2.3. Other assigned/identified product hazards

None known.

2.4. Other hazards which do not result in classification

May be harmful if swallowed.

SECTION 3: Composition/information on ingredients

This material is a mixture.

Ingredient	CAS Nbr	% by Weight
Silane treated glass	None	90 - 99.9
Potassium persulphate	7727-21-1	< 0.2

SECTION 4: First aid measures**4.1. Description of first aid measures****Inhalation**

Remove person to fresh air. If you feel unwell, get medical attention.

Skin contact

Immediately wash with soap and water. Remove contaminated clothing and wash before reuse. If signs/symptoms develop, get medical attention.

Eye contact

Flush with large amounts of water. Remove contact lenses if easy to do. Continue rinsing. If signs/symptoms persist, get medical attention.

If swallowed

Rinse mouth. If you feel unwell, get medical attention.

4.2. Most important symptoms and effects, both acute and delayed

Allergic respiratory reaction (difficulty breathing, wheezing, cough, and tightness of chest). Allergic skin reaction (redness, swelling, blistering, and itching).

4.3. Indication of any immediate medical attention and special treatment required

Not applicable

SECTION 5: Fire-fighting measures**5.1. Suitable extinguishing media**

In case of fire: Use a fire fighting agent suitable for ordinary combustible material such as water or foam to extinguish.

5.2. Special hazards arising from the substance or mixture

None inherent in this product.

Hazardous Decomposition or By-Products**Substance**

Carbon monoxide.
Carbon dioxide.

Condition

During combustion.
During combustion.

5.3. Special protective actions for fire-fighters

Wear full protective clothing, including helmet, self-contained, positive pressure or pressure demand breathing apparatus, bunker coat and pants, bands around arms, waist and legs, face mask, and protective covering for exposed areas of the head.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

Evacuate area. Ventilate the area with fresh air. For large spill, or spills in confined spaces, provide mechanical ventilation to disperse or exhaust vapors, in accordance with good industrial hygiene practice. Use personal protective equipment based on the results of an exposure assessment. Refer to Section 8 for PPE recommendations. If anticipated exposure resulting from an accidental release exceeds the protective capabilities of the PPE listed in Section 8, or are unknown, select PPE that offers an appropriate level of protection. Consider the physical and chemical hazards of the material when doing so. Examples of PPE ensembles for emergency response could include wearing bunker gear for a release of flammable material; wearing chemical protective clothing if the spilled material is a corrosive, a sensitizer, a significant dermal irritant, or can be absorbed through the skin; or donning a positive pressure supplied-air respirator for chemicals with inhalation hazards. For information regarding physical and health hazards, refer to sections 2 and 11 of the SDS.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Collect as much of the spilled material as possible. Place in a closed container approved for transportation by appropriate authorities. Clean up residue. Seal the container. Dispose of collected material as soon as possible in accordance with applicable local/regional/national/international regulations.

SECTION 7: Handling and storage**7.1. Precautions for safe handling**

Avoid breathing dust/fume/gas/mist/vapours/spray. Do not eat, drink or smoke when using this product. Wash thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse. Do not get in eyes. A no-touch technique is recommended. If skin contact occurs, wash skin with soap and water. If product contacts glove, remove and discard glove, wash hands immediately with soap and water and then re-glove.

7.2. Conditions for safe storage including any incompatibilities

No special storage requirements.

SECTION 8: Exposure controls/personal protection**8.1 Control parameters****Occupational exposure limits**

If a component is disclosed in section 3 but does not appear in the table below, an occupational exposure limit is not available for the component.

Ingredient	CAS Nbr	Agency	Limit type	Additional comments
PERSULFATE COMPOUNDS	7727-21-1	ACGIH	TWA(as persulfate):0.1 mg/m3	
Potassium persulphate	7727-21-1	Australia OELs	Peak limit:0.01 mg/m3	

ACGIH : American Conference of Governmental Industrial Hygienists

AIHA : American Industrial Hygiene Association

Australia OELs : Australia. Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment

CMRG : Chemical Manufacturer's Recommended Guidelines

TWA: Time-Weighted-Average
 STEL: Short Term Exposure Limit
 CEIL: Ceiling
 Sen: Sensitiser
 Sk: Absorption through the skin may be a significant source of exposure.

8.2. Exposure controls

8.2.1. Engineering controls

Use in a well-ventilated area.

8.2.2. Personal protective equipment (PPE)

Eye/face protection

Select and use eye/face protection to prevent contact based on the results of an exposure assessment. The following eye/face protection(s) are recommended:
 Safety glasses with side shields.

Select and use eye protection in accordance with AS/NZS 1336. Eye protection should comply with the performance specifications of AS/NZS 1337.

Skin/hand protection

See Section 7.1 for additional information on skin protection.

Respiratory protection

None required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Solid.
Specific Physical Form:	Coarse Powder
Colour	White
Odour	odour less
Odour threshold	<i>No data available.</i>
pH	<i>Not applicable.</i>
Melting point/Freezing point	<i>No data available.</i>
Boiling point/Initial boiling point/Boiling range	<i>Not applicable.</i>
Flash point	No flash point
Evaporation rate	<i>Not applicable.</i>
Flammability	Not applicable.
Flammable Limits(LEL)	<i>Not applicable.</i>
Flammable Limits(UEL)	<i>Not applicable.</i>
Vapour pressure	<i>Not applicable.</i>
Relative Vapor Density	<i>Not applicable.</i>
Density	2.8 g/cm ³
Relative density	2.8 [Ref Std: WATER=1]
Water solubility	<i>Not applicable.</i>
Solubility- non-water	<i>No data available.</i>
Partition coefficient: n-octanol/water	<i>No data available.</i>
Autoignition temperature	<i>No data available.</i>
Decomposition temperature	<i>No data available.</i>

Kinematic Viscosity	<i>Not applicable.</i>
Volatile organic compounds (VOC)	<i>Not applicable.</i>
Percent volatile	<i>Not applicable.</i>
VOC less H2O & exempt solvents	<i>Not applicable.</i>
Molecular weight	<i>No data available.</i>

Particle Characteristics	<i>Not applicable.</i>
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SECTION 10: Stability and reactivity

10.1 Reactivity

This material is considered to be non reactive under normal use conditions

10.2 Chemical stability

Stable.

10.3. Conditions to avoid

None known.

10.4. Possibility of hazardous reactions

Hazardous polymerisation will not occur.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

Substance

None known.

Condition

SECTION 11: Toxicological information

The information below may not be consistent with the material classification in Section 2 if specific ingredient classifications are mandated by a competent authority. In addition, toxicological data on ingredients may not be reflected in the material classification and/or the signs and symptoms of exposure, because an ingredient may be present below the threshold for labelling, an ingredient may not be available for exposure, or the data may not be relevant to the material as a whole.

11.1 Information on Toxicological effects

Signs and Symptoms of Exposure

Based on test data and/or information on the components, this material may produce the following health effects:

Inhalation

Allergic respiratory reaction: Signs/symptoms may include difficulty breathing, wheezing, cough, and tightness of chest.

Skin contact

Mechanical skin irritation: Signs/symptoms may include abrasion, redness, pain, and itching. Allergic skin reaction (non-photo induced): Signs/symptoms may include redness, swelling, blistering, and itching.

Eye contact

Mechanical eye irritation: Signs/symptoms may include pain, redness, tearing and corneal abrasion.

Ingestion

May be harmful if swallowed.

Gastrointestinal irritation: Signs/symptoms may include abdominal pain, stomach upset, nausea, vomiting and diarrhoea.

Toxicological Data

If a component is disclosed in section 3 but does not appear in a table below, either no data are available for that endpoint or the data are not sufficient for classification.

Acute Toxicity

Name	Route	Species	Value
Overall product	Ingestion		No data available; calculated ATE >2,000 - =5,000 mg/kg
Silane treated glass	Dermal		LD50 estimated to be > 5,000 mg/kg
Silane treated glass	Ingestion		LD50 estimated to be 2,000 - 5,000 mg/kg
Potassium persulphate	Dermal	Rabbit	LD50 > 10,000 mg/kg
Potassium persulphate	Ingestion	Rat	LD50 1,130 mg/kg
Potassium persulphate	Inhalation-Dust/Mist (4 hours)	similar compounds	LC50 > 5.1 mg/l

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Silane treated glass	Professional judgement	No significant irritation
Potassium persulphate	Rabbit	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
Silane treated glass	Professional judgement	No significant irritation
Potassium persulphate	Rabbit	No significant irritation

Skin Sensitisation

Name	Species	Value
Potassium persulphate	Mouse	Sensitising

Respiratory Sensitisation

Name	Species	Value
Potassium persulphate	Human	Sensitising

Germ Cell Mutagenicity

Name	Route	Value
Potassium persulphate	In Vitro	Not mutagenic

Carcinogenicity

For the component/components, either no data are currently available or the data are not sufficient for classification.

Reproductive Toxicity

Reproductive and/or Developmental Effects

For the component/components, either no data are currently available or the data are not sufficient for classification.

Target Organ(s)

Specific Target Organ Toxicity - single exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Potassium persulphate	Inhalation	respiratory irritation	May cause respiratory irritation	Human and animal	NOAEL Not available	

Specific Target Organ Toxicity - repeated exposure

For the component/components, either no data are currently available or the data are not sufficient for classification.

Aspiration Hazard

For the component/components, either no data are currently available or the data are not sufficient for classification.

Exposure Levels

Refer Section 8.1 Control Parameters of this Safety Data Sheet.

Interactive Effects

Not Determined

SECTION 12: Ecological information

The information below may not be consistent with the material classification in Section 2 if specific ingredient classifications are mandated by a competent authority. Additional information leading to material classification in Section 2 is available upon request. In addition, environmental fate and effects data on ingredients may not be reflected in this section because an ingredient is present below the threshold for labelling, an ingredient is not expected to be available for exposure, or the data is considered not relevant to the material as a whole.

12.1. Toxicity**Acute aquatic hazard:**

Not acutely toxic to aquatic life by GHS criteria.

Chronic aquatic hazard:

Not chronically toxic to aquatic life by GHS criteria.

No product test data available.

Material	CAS Number	Organism	Type	Exposure	Test endpoint	Test result
Silane treated glass	None	N/A	Data not available or insufficient for classification	N/A	N/A	N/A
Potassium persulphate	7727-21-1	Algae or other aquatic plants	Estimated	72 hours	EC50	320 mg/l
Potassium persulphate	7727-21-1	Copepod	Estimated	48 hours	LC50	21.22 mg/l
Potassium persulphate	7727-21-1	Rainbow trout	Estimated	96 hours	LC50	76.3 mg/l
Potassium persulphate	7727-21-1	Algae or other aquatic plants	Estimated	72 hours	NOEC	32 mg/l

12.2. Persistence and degradability

Material	CAS Number	Test type	Duration	Study Type	Test result	Protocol
Silane treated glass	None	Data not available-insufficient	N/A	N/A	N/A	N/A

Vitremer™ Core Buildup/Restorative Powder (3303)

Potassium persulphate	7727-21-1	Data not available-insufficient	N/A	N/A	N/A	N/A
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12.3 : Bioaccumulative potential

Material	CAS Number	Test type	Duration	Study Type	Test result	Protocol
Silane treated glass	None	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Potassium persulphate	7727-21-1	Data not available or insufficient for classification	N/A	N/A	N/A	N/A

12.4. Mobility in soil

Please contact manufacturer for more details

12.5 Other adverse effects

No information available.

SECTION 13: Disposal considerations**13.1. Disposal methods**

Dispose of contents/ container in accordance with the local/regional/national/international regulations.

Dispose of waste product in a permitted industrial waste facility. As a disposal alternative, incinerate in a permitted waste incineration facility.

SECTION 14: Transport Information**Australian Dangerous Goods Code (ADG) - Road/Rail Transport**

UN No.: Not applicable.

Proper shipping name: Not applicable.

Class/Division: Not applicable.

Sub Risk: Not applicable.

Packing Group: Not applicable.

Hazchem Code: Not applicable

IERG: Not applicable.

International Air Transport Association (IATA) - Air Transport

UN No.: Not applicable.

Proper shipping name: Not applicable.

Class/Division: Not applicable.

Sub Risk: Not applicable.

Packing Group: Not applicable.

International Maritime Dangerous Goods Code (IMDG)- Marine Transport

UN No.: Not applicable.

Proper shipping name: Not applicable.

Class/Division: Not applicable.

Sub Risk: Not applicable.

Packing Group: Not applicable.

Marine Pollutant: Not applicable.

SECTION 15: Regulatory information

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

Australian Inventory Status:

This product is regulated by the Therapeutics Goods Administration and is exempt from compliance with the Industrial Chemicals (Notification and Assessment) Act 1989 as amended.

SECTION 16: Other information

Revision information:

Complete document review.

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Greenguard ® is a United States based program. The 'Low VOC' reference related to United States Federal and State regulations exemptions for some solvents.

Solventum Australia SDSs are available at Solventum.com