

Material Safety Data Sheet Cover-Sheet – This page provides additional New Zealand specific information for this product and must be read in conjunction with the Safety Data Sheet (SDS) attached

Product Name: Filtek One Bulk Fill Restorative

Manufacturer: 3M Australia

SDS Expiry: 3 November 2026

Supplier Details: Henry Schein New Zealand
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Emergency Contacts: Poisons/Hazardous Chemical Info Centre –
0800POISON/0800764766 (24 Hours)
Phone 111 for Fire, Ambulance or Police

HSNO Class/Category: 6

HSNO Group Standard: Dental Products Subsidiary Hazard Group Standard 2020
HSR002558

Statements/Pictograms: As per attached Safety Data Sheet (SDS)

Date Prepared: This coversheet was prepared – May 2023

This SDS coversheet has been produced by Henry Schein NZ and has been prepared in accordance with NZ EPA advice on making overseas SDS compliant to HSNO Act. The above information is based on the present state of our knowledge of the product at the time of publication. It is given in good faith, no warranty is implied with respect to the quality or the specifications of the product. Users must satisfy that the product is entirely suitable for their purpose. The SDS and this coversheet may be revised from time to time, please ensure you have a current copy.



Safety Data Sheet

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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

3M™ Filtek™ One Bulk Fill Restorative

Product Identification Numbers

70-2014-0467-3	70-2014-0468-1	70-2014-0469-9	70-2014-0470-7	70-2014-0471-5
70-2014-0472-3	70-2014-0473-1	70-2014-0474-9	70-2014-0475-6	70-2014-0476-4
70-2014-0477-2	70-2014-0478-0			

1.2. Recommended use and restrictions on use

Recommended use

Dental Restorative, Restrictions on Use: For use only by dental professionals in approved indications

1.3. Supplier's details

Address: 3M Australia - Building A, 1 Rivett Road, North Ryde NSW 2113
Telephone: 136 136
E Mail: productinfo.au@mmm.com
Website: www.3m.com.au

1.4. Emergency telephone number

EMERGENCY: 1800 097 146 (Australia only)

SECTION 2: Hazard identification

This product is 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

Skin Sensitizer: Category 1B.

2.2. Label elements

The label elements below were prepared in accordance with the Code of Practice on Preparation of Safety Data Sheets for Hazardous Chemicals (Safe Work Australia, December 2011). This information may be different from the actual product label.

Signal word

Warning

Symbols

Exclamation mark |

Pictograms**Hazard statements**

H317 May cause an allergic skin reaction.

Precautionary statements**Prevention:**

P272 Contaminated work clothing should not be allowed out of the workplace.
 P280E Wear protective gloves.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
 P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.
 P362 + P364 Take off contaminated clothing and wash it before reuse.

Disposal:

P501 Dispose of contents/container in accordance with applicable local/regional/national/international regulations.

2.3. Other assigned/identified product hazards

A similar mixture has been tested for acute oral toxicity and the test results do not meet the criteria for classification. A similar mixture has been tested for acute dermal toxicity and the test results do not meet the criteria for classification.

2.4. Other hazards which do not result in classification

Toxic to aquatic life.
 Harmful to aquatic life with long lasting effects.

SECTION 3: Composition/information on ingredients

This material is a mixture.

Ingredient	CAS Nbr	% by Weight
Silane Treated Ceramic	444758-98-9	60 - 70
Aromatic Urethane Dimethacrylate	1431303-59-1	10 - 20
1,12-Dodecane Dimethacrylate (DDDMA)	72829-09-5	< 10
Diurethane Dimethacrylate (UDMA)	72869-86-4	1 - 10
Silane Treated Silica	248596-91-0	1 - 10
Ytterbium Fluoride (YbF3)	13760-80-0	1 - 10
Silane Treated Zirconia	None	< 5
Water	7732-18-5	< 5

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 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

<u>Substance</u>	<u>Condition</u>
Carbon monoxide.	During combustion.
Carbon dioxide.	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. Refer to other sections of this SDS for information regarding physical and health hazards, respiratory protection, ventilation, and personal protective equipment.

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 of dust created by cutting, sanding, grinding or machining. A no-touch technique is recommended. If skin contact occurs, wash skin with soap and water. Acrylates may penetrate commonly-used gloves. If product contacts glove, remove and discard glove, wash hands immediately with soap and water and then re-glove. 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. Avoid release to the environment. Wash contaminated clothing before reuse. Avoid contact with oxidising agents (eg. chlorine, chromic acid etc.) Do not get in eyes.

7.2. Conditions for safe storage including any incompatibilities

Store away from heat. Store away from oxidising agents.

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

No occupational exposure limit values exist for any of the components listed in Section 3 of this Safety Data Sheet.

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:	Paste
Colour	White
Odour	Slight Acrylate
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>No data available.</i>
Flammability (solid, gas)	Not classified
Flammable Limits(LEL)	<i>Not applicable.</i>
Flammable Limits(UEL)	<i>Not applicable.</i>
Vapour pressure	<i>Not applicable.</i>
Vapor Density and/or Relative Vapor Density	<i>Not applicable.</i>
Density	1.9 g/cm ³
Relative density	1.9 [Ref.Std:WATER=1]
Water solubility	Negligible
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>
Viscosity/Kinematic Viscosity	<i>No data available.</i>
Volatile organic compounds (VOC)	
Percent volatile	
VOC less H ₂ O & exempt solvents	
Molecular weight	<i>Not applicable.</i>

Nanoparticles

This material contains nanoparticles.

SECTION 10: Stability and reactivity**10.1 Reactivity**

This material may be reactive with certain agents under certain conditions - see the remaining headings in this section

10.2 Chemical stability

Stable.

10.3. Conditions to avoid

Heat.

10.4. Possibility of hazardous reactions

Hazardous polymerisation will not occur.

10.5 Incompatible materials

Strong oxidising agents.

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

Respiratory tract irritation: Signs/symptoms may include cough, sneezing, nasal discharge, headache, hoarseness, and nose and throat pain.

Skin contact

Contact with the skin during product use is not expected to result in significant irritation. Allergic skin reaction (non-photo induced): Signs/symptoms may include redness, swelling, blistering, and itching.

Eye contact

Contact with the eyes during product use is not expected to result in significant irritation.

Ingestion

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	Dermal	Professional judgement	LD50 Not applicable
Overall product	Ingestion	Rat	LD50 > 2,000 mg/kg
Silane Treated Ceramic	Dermal		LD50 estimated to be > 5,000 mg/kg
Silane Treated Ceramic	Ingestion		LD50 estimated to be 2,000 - 5,000 mg/kg
Aromatic Urethane Dimethacrylate	Dermal	Professional judgement	LD50 estimated to be 2,000 - 5,000 mg/kg
Aromatic Urethane Dimethacrylate	Ingestion	Rat	LD50 > 2,000 mg/kg
Silane Treated Zirconia	Dermal		LD50 estimated to be > 5,000 mg/kg
Silane Treated Zirconia	Ingestion		LD50 estimated to be 2,000 - 5,000 mg/kg
Diurethane Dimethacrylate (UDMA)	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Diurethane Dimethacrylate (UDMA)	Ingestion	Rat	LD50 > 5,000 mg/kg
Ytterbium Fluoride (YbF3)	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Ytterbium Fluoride (YbF3)	Ingestion	Rat	LD50 > 5,000 mg/kg
1,12-Dodecane Dimethacrylate (DDDMA)	Dermal	Professional judgement	LD50 estimated to be 2,000 - 5,000 mg/kg
1,12-Dodecane Dimethacrylate (DDDMA)	Ingestion	similar compounds	LD50 2000-5000 mg/kg
Silane Treated Silica	Dermal		LD50 estimated to be > 5,000 mg/kg
Silane Treated Silica	Ingestion		LD50 estimated to be > 5,000 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Silane Treated Ceramic	similar compounds	No significant irritation
Aromatic Urethane Dimethacrylate	In vitro data	No significant irritation
Silane Treated Zirconia	Rabbit	No significant irritation
Silane Treated Silica	Professional judgement	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
Silane Treated Ceramic	similar compounds	Mild irritant
Aromatic Urethane Dimethacrylate	In vitro data	No significant irritation
Silane Treated Zirconia	Rabbit	Mild irritant
Ytterbium Fluoride (YbF3)	Professional judgement	Mild irritant
Silane Treated Silica	Professional judgement	No significant irritation

Skin Sensitisation

Name	Species	Value
Silane Treated Ceramic	similar compounds	Not classified
Diurethane Dimethacrylate (UDMA)	Guinea pig	Sensitising

Respiratory Sensitisation

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

Germ Cell Mutagenicity

Name	Route	Value
Aromatic Urethane Dimethacrylate	In Vitro	Not mutagenic
Silane Treated Zirconia	In Vitro	Some positive data exist, but the data are not sufficient for classification

Carcinogenicity

Name	Route	Species	Value
Silane Treated Ceramic	Inhalation	similar compounds	Some positive data exist, but the data are not sufficient for classification
Silane Treated Zirconia	Inhalation	Multiple animal species	Some positive data exist, but 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**

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

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Silane Treated Ceramic	Inhalation	pulmonary fibrosis	Not classified	similar compounds	NOAEL Not available	
Silane Treated Zirconia	Inhalation	pulmonary fibrosis	Not classified	Multiple animal species	NOAEL Not available	
Silane Treated Zirconia	Inhalation	respiratory system	Not classified	Human	NOAEL Not available	occupational exposure

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:

GHS Acute 2: Toxic to aquatic life.

Chronic aquatic hazard:

GHS Chronic 3: Harmful to aquatic life with long lasting effects.

No product test data available.

Material	CAS Number	Organism	Type	Exposure	Test endpoint	Test result
Silane Treated Ceramic	444758-98-9		Data not available or insufficient for classification			N/A
Aromatic Urethane Dimethacrylate	1431303-59-1		Data not available or insufficient for classification			N/A
1,12-Dodecane Dimethacrylate (DDDMA)	72829-09-5	Green Algae	Experimental	72 hours	EC50	17 ug/l
1,12-Dodecane Dimethacrylate (DDDMA)	72829-09-5	Water flea	Experimental	48 hours	EC50	>100 mg/l
1,12-Dodecane Dimethacrylate (DDDMA)	72829-09-5	Green Algae	Experimental	72 hours	EC10	6.4 ug/l
Diurethane Dimethacrylate (UDMA)	72869-86-4	Green algae	Endpoint not reached	72 hours	ErC50	>100 mg/l
Diurethane Dimethacrylate (UDMA)	72869-86-4	Water flea	Experimental	48 hours	EC50	>100 mg/l
Diurethane Dimethacrylate (UDMA)	72869-86-4	Zebra Fish	Experimental	96 hours	LC50	10.1 mg/l
Diurethane Dimethacrylate (UDMA)	72869-86-4	Green algae	Endpoint not reached	72 hours	ErC10	>100 mg/l
Silane Treated Silica	248596-91-0		Data not available or			N/A

			insufficient for classification			
Ytterbium Fluoride (YbF3)	13760-80-0	Water flea	Experimental	48 hours	No tox obs at lmt of water sol	>100 mg/l
Silane Treated Zirconia	None		Data not available or insufficient for classification			N/A

12.2. Persistence and degradability

Material	CAS Number	Test type	Duration	Study Type	Test result	Protocol
Silane Treated Ceramic	444758-98-9	Data not available-insufficient			N/A	
Aromatic Urethane Dimethacrylate	1431303-59-1	Data not available-insufficient			N/A	
1,12-Dodecane Dimethacrylate (DDDMA)	72829-09-5	Experimental Biodegradation	28 days	CO2 evolution	97.3 %CO2 evolution/THC O2 evolution	OECD 301B - Modified sturm or CO2
Diurethane Dimethacrylate (UDMA)	72869-86-4	Experimental Biodegradation	28 days	CO2 evolution	22 %CO2 evolution/THC O2 evolution (does not pass 10-day window)	OECD 301B - Modified sturm or CO2
Silane Treated Silica	248596-91-0	Data not available-insufficient			N/A	
Ytterbium Fluoride (YbF3)	13760-80-0	Data not available-insufficient			N/A	
Silane Treated Zirconia	None	Data not available-insufficient			N/A	

12.3 : Bioaccumulative potential

Material	CAS Number	Test type	Duration	Study Type	Test result	Protocol
Silane Treated Ceramic	444758-98-9	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Aromatic Urethane Dimethacrylate	1431303-59-1	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
1,12-Dodecane Dimethacrylate (DDDMA)	72829-09-5	Estimated Bioconcentration		Bioaccumulation factor	6.6	Estimated: Bioconcentration factor
Diurethane Dimethacrylate (UDMA)	72869-86-4	Experimental Bioconcentration		Log Kow	3.39	Non-standard method

Silane Treated Silica	248596-91-0	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Ytterbium Fluoride (YbF3)	13760-80-0	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Silane Treated Zirconia	None	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 completely cured (or polymerized) material in a permitted industrial waste facility. As a disposal alternative, incinerate uncured product in a permitted waste incineration facility. If no other disposal options are available, waste product that has been completely cured or polymerized may be placed in a landfill properly designed for industrial waste.

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.

DISCLAIMER: The information on this Safety Data Sheet is based on our experience and is correct to the best of our knowledge at the date of publication, but we do not accept any liability for any loss, damage or injury resulting from its use (except as required by law). The information may not be valid for any use not referred to in this Safety Data Sheet or use of the product in combination with other materials. For these reasons, it is important that customers carry out their own test to satisfy themselves as to the suitability of the product for their own intended applications.

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

3M Australia SDSs are available at www.3m.com.au