

Safety Data Sheet

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This Safety Data Sheet has been prepared in accordance with the New Zealand, Hazardous Substances (Safety Data Sheets) Notice 2017.

SECTION 1: Identification

1.1. Product identifier

3MTM FiltekTM Supreme Flowable

Product Identification Numbers

70-2014-0776-7	70-2014-0777-5	70-2014-0779-1	70-2014-0780-9	70-2014-0781-7
70-2014-0849-2	70-2014-0873-2	70-2014-0874-0	70-2014-0875-7	70-2014-0876-5
70-2014-0877-3	70-2014-0878-1	70-2014-0879-9	70-2014-0889-8	

1.2. Recommended use and restrictions on use

Recommended use

Dental Product, Composite restorative material

For use only by dental professionals.

1.3. Supplier's details

Address: 3M New Zealand Ltd, 94 Apollo Drive, Rosedale 0632, Auckland

Telephone: (09) 477 4040

E Mail: innovation@nz.mmm.com

Website: 3m.co.nz

1.4. Emergency telephone number

24 hr Medical Emergency, National Poisons Centre, 0800 764 766 (0800 POISON)

SECTION 2: Hazard identification

Classified as hazardous in accordance with the relevant criteria of the HSNO Act 1996, the Hazardous Substances (Classification) Notice 2017 and Hazardous Substances (Minimum Degrees of Hazard) Notice 2017. Refer to Section 14 of this Safety Data Sheet for product Dangerous Goods Classification.

2.1. Classification of the substance or mixture

GHS	HSNO
Acute Toxicity (oral): Category 5	6.1E Acute toxicity (oral)

Skin Sensitiser: Category 1 6.5B Skin sensitiser

2.2. Label elements SIGNAL WORD

WARNING!

Symbols:

Exclamation mark |

Pictograms



HAZARD STATEMENTS:

H303 May be harmful if swallowed. H317 May cause an allergic skin reaction.

PRECAUTIONARY STATEMENTS

Prevention:

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P280E Wear protective gloves.

P272A Contaminated work clothing must not be allowed out of the workplace.

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.
P321 Specific treatment (see Notes to Physician on this label).

P312 Call a POISON CENTRE or doctor/physician if you feel unwell.

Disposal:

P501 Dispose of contents/container in accordance with applicable

 $local/regional/national/international\ regulations.$

SECTION 3: Composition/information on ingredients

Ingredient	CAS Nbr	% by Weight
Silane Treated Ceramic	444758-98-9	50 - 60
Substituted Dimethacrylate	27689-12-9	15 - 25
Silane Treated Silica	248596-91-0	5 - 10
Triethylene Glycol Dimethacrylate (TEGDMA)	109-16-0	5 - 10
Ytterbium fluoride (YbF3)	13760-80-0	< 5
Reacted Polycaprolactone Polymer	None	< 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.

Eve 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

See Section 11.1 Information on toxicological effects

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

SubstanceConditionCarbon 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.

5.4. Hazchem code: Not applicable.

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

Refer to Section 15 - Controls for more information

7.1. Precautions for safe handling

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. 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.

7.2. Conditions for safe storage including any incompatibilities

No special storage requirements.

7.3. Certified handler

Not required

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
Fluorides	13760-80-0	ACGIH	TWA(as F):2.5 mg/m3	A4: Not class. as human
				carcinogin

Fluorides 13760-80-0 New Zealand TWA(as F)(8 hours): 2.5

WES mg/m3

ACGIH: American Conference of Governmental Industrial Hygienists

AIHA: American Industrial Hygiene Association

CMRG: Chemical Manufacturer's Recommended Guidelines New Zealand WES: New Zealand Workplace Exposure Standards.

TWA: Time-Weighted-Average STEL: Short Term Exposure Limit

ppm: parts per million

mg/m³: milligrams per cubic metre

CEIL: Ceiling

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.

Refer AS/NZS 1336 - Recommended practices for occupational eye protection and for performance specifications AS/NZS 1337, Parts 1 - 6 - Personal eye-protection.

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

Throt mation on basic physical and enemical properties				
Physical state	Solid.			
Specific Physical Form:	Paste			
Colour	Tooth			
Odour	Slight Acrylate			
Odour threshold	No data available.			
рН	Not applicable.			
Melting point/Freezing point	No data available.			
Boiling point/Initial boiling point/Boiling range	Not applicable.			
Flash point	No flash point			
Evaporation rate	Not applicable.			
Flammability (solid, gas)	Not classified			
Flammable Limits(LEL)	Not applicable.			
Flammable Limits(UEL)	Not applicable.			
Vapour pressure	Not applicable.			
Vapor Density and/or Relative Vapor Density	Not applicable.			
Density	1.5 g/cm3			
Relative density	1.5 [Ref Std:WATER=1]			
Water solubility	Negligible			
Solubility- non-water	No data available.			
Partition coefficient: n-octanol/water	Not applicable.			
Autoignition temperature	No data available.			
Decomposition temperature	No data available.			
Viscosity/Kinematic Viscosity	No data available.			
Volatile organic compounds (VOC)				
Percent volatile				
VOC less H2O & exempt solvents	No data available.			
Molecular weight	No data available.			
	ı			

Nanoparticles

This material contains nanoparticles.

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 Possibility of hazardous reactions

Hazardous polymerisation will not occur.

10.4 Conditions to avoid

None known.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products Substance

Condition

None known.

Refer to Section 5.2 for hazardous decomposition products during combustion.

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

This product may have a characteristic odour; however, no adverse health effects are anticipated.

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

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
		Species	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
Overall product	Dermal		No data available; calculated ATE >5,000 mg/kg
Overall product	Ingestion		No data available; calculated ATE2,000 - 5,000 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
Substituted Dimethacrylate	Dermal	Professio nal judgeme nt	LD50 estimated to be > 5,000 mg/kg
Substituted Dimethacrylate	Ingestion	Rat	LD50 > 17,600 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
Triethylene Glycol Dimethacrylate (TEGDMA)	Dermal	Professio nal judgeme	LD50 estimated to be > 5,000 mg/kg

		nt	
Triethylene Glycol Dimethacrylate (TEGDMA)	Ingestion	Rat	LD50 10,837 mg/kg
Ytterbium fluoride (YbF3)	Dermal	Professio	LD50 estimated to be > 5,000 mg/kg
		nal	
		judgeme	
		nt	
Ytterbium fluoride (YbF3)	Ingestion	Rat	LD50 > 5,000 mg/kg
Reacted Polycaprolactone Polymer	Dermal	Professio	LD50 estimated to be 2,000 - 5,000 mg/kg
		nal	
		judgeme	
		nt	
Reacted Polycaprolactone Polymer	Ingestion	similar	LD50 estimated to be 2,000 - 5,000 mg/kg
		compoun	
		ds	

 \overline{ATE} = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Silane Treated Ceramic	similar	No significant irritation
	compoun	
	ds	
Substituted Dimethacrylate	Rabbit	No significant irritation
Silane Treated Silica	Professio	No significant irritation
	nal	
	judgemen	
	t	
Triethylene Glycol Dimethacrylate (TEGDMA)	Guinea	Mild irritant
	pig	

Serious Eye Damage/Irritation

Name	Species	Value
	Process	
	ļ.,.,	
Silane Treated Ceramic	similar	Mild irritant
	compoun	
	ds	
Substituted Dimethacrylate	Rabbit	Mild irritant
Silane Treated Silica	Professio	No significant irritation
	nal	
	judgemen	
	t	
Triethylene Glycol Dimethacrylate (TEGDMA)	Professio	Moderate irritant
	nal	
	judgemen	
	t	
Ytterbium fluoride (YbF3)	Professio	Mild irritant
	nal	
	judgemen	
	t	

Sensitisation:

Skin Sensitisation

Name	Species	Value
Silane Treated Ceramic	similar	Not classified
	compoun	
	ds	
Substituted Dimethacrylate	Guinea	Not classified
	pig	
Triethylene Glycol Dimethacrylate (TEGDMA)	Human	Sensitising
	and	
	animal	

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
Substituted Dimethacrylate	In Vitro	Not mutagenic
Triethylene Glycol Dimethacrylate (TEGDMA)		Some positive data exist, but the data are not sufficient for classification

Carcinogenicity

Name	Route	Species	Value
Silane Treated Ceramic	Inhalation	similar compoun ds	Some positive data exist, but the data are not sufficient for classification
Triethylene Glycol Dimethacrylate (TEGDMA)	Dermal	Mouse	Not carcinogenic

Reproductive Toxicity

Reproductive and/or Developmental Effects

Name	Route	Value	Species	Test result	Exposure Duration		
Triethylene Glycol Dimethacrylate (TEGDMA)	Ingestion	Not classified for female reproduction	Mouse	NOAEL 1 mg/kg/day	1 generation		
Triethylene Glycol Dimethacrylate (TEGDMA)	Ingestion	Not classified for male reproduction	Mouse	NOAEL 1 mg/kg/day	1 generation		
Triethylene Glycol Dimethacrylate (TEGDMA)	Ingestion	Not classified for development	Mouse	NOAEL 1 mg/kg/day	1 generation		

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 compoun ds	NOAEL Not available	
Triethylene Glycol Dimethacrylate (TEGDMA)	Dermal	kidney and/or bladder blood	Not classified	Mouse	NOAEL 833 mg/kg/day	78 weeks

Aspiration Hazard

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

Please contact the address or phone number listed on the first page of the SDS for additional toxicological information on this material and/or its components.

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

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			
Substituted Dimethacrylate	27689-12-9	Green algae	Experimental	72 hours	EC50	>100 mg/l
Substituted Dimethacrylate	27689-12-9	Water flea	Experimental	48 hours	EC50	>100 mg/l
Substituted Dimethacrylate	27689-12-9	Green algae	Experimental	72 hours	NOEC	>100 mg/l
Silane Treated Silica	248596-91-0		Data not available or insufficient for classification			
Triethylene Glycol Dimethacrylate (TEGDMA)	109-16-0	Zebra Fish	Experimental	96 hours	LC50	16.4 mg/l
Triethylene Glycol Dimethacrylate (TEGDMA)	109-16-0	Green Algae	Experimental	72 hours	EC50	>100 mg/l
Triethylene Glycol Dimethacrylate (TEGDMA)	109-16-0	Water flea	Experimental	21 days	NOEC	32 mg/l
Triethylene Glycol Dimethacrylate (TEGDMA)	109-16-0	Green algae	Experimental	72 hours	NOEC	18.6 mg/l
Ytterbium fluoride (YbF3)	13760-80-0	Water flea	Experimental	48 hours	No tox obs at lmt of water sol	>100 mg/l
Reacted Polycaprolacto ne Polymer	None		Data not available or insufficient for classification			

12.2. Persistence and degradability

Material	CAS Number	Test type	Duration	Study Type	Test result	Protocol
Silane Treated	444758-98-9	Data not			N/A	
Ceramic		availbl-				
		insufficient				
Substituted	27689-12-9	Experimental	28 days	CO2 evolution	7-12 % weight	OECD 301B - Modified
Dimethacrylate		Biodegradation				sturm or CO2
Silane Treated	248596-91-0	Data not			N/A	
Silica		availbl-				
		insufficient				
Triethylene	109-16-0	Experimental	28 days	CO2 evolution	85 % weight	OECD 301B - Modified
Glycol		Biodegradation				sturm or CO2
Dimethacrylate						

(TEGDMA)					
Ytterbium	13760-80-0	Data not		N/A	
fluoride (YbF3)		availbl-			
		insufficient			
Reacted	None	Data not		N/A	
Polycaprolacto		availbl-			
ne Polymer		insufficient			

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	N/A	N/A	N/A	N/A
		insufficient for classification				
Substituted	27689-12-9	Estimated		Log Kow	7.61	Estimated: Octanol-
Dimethacrylate		Bioconcentrati on				water partition coefficient
Silane Treated Silica	248596-91-0	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Triethylene Glycol Dimethacrylate (TEGDMA)	109-16-0	Experimental Bioconcentrati on		Log Kow	2.3	Other methods
Ytterbium fluoride (YbF3)	13760-80-0	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Reacted Polycaprolacto ne Polymer	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

In accordance with the Hazardous Substances (Disposal) Notice 2017 and the relevant criteria of the HSNO Act 1996.

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.

Packaging (that may or may not contain any residual substance) may be lawfully disposed of by householders or other consumers through public or commercial waste collection services.

SECTION 14: Transport Information

New Zealand Land Transport Rule: Dangerous Goods - 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

HSNO Approval number HSR002558

Group standard name Dental Products (Subsidiary Hazard) Group Standard 2017

HSNO Hazard classification Refer to Section 2: Hazard identification

NZ Inventory of Chemicals (NZIoC) Status

All applicable chemical ingredients in this material are in compliance with NZIoC listing requirements.

Controls in accordance with the Health and Safety at Work (Hazardous Substances) Regulations 2017

Certified handler
Location Compliance Certificate
Hazardous atmosphere zone
Not required
Not required
Not required
Not required
Not required

Emergency response plan 1,000 L or 1,000 kg (for a HSNO 6.1D, 6.5A, 6.5B, 9.1B or 9.1C substance);

or 10,000 L or 10,000 kg (for a HSNO 6.6A, 6.8A, 6.9A, 8.3A, 9.1D

substance)

Secondary containment 1,000 L or 1,000 kg (for a HSNO 6.1D, 6.5A, 6.5B, 9.1B or 9.1C substance);

or 10,000 L or 10,000 kg (for a HSNO 6.6A, 6.8A, 6.9A, 8.3A, 9.1D

substance)

Tracking Not required Warning signage Not required

SECTION 16: Other information

Revision information:

Initial issue.

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3M TM Filtek TM Supre	eme Flowable	

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Key to abbreviations and acronyms

GHS means the Globally Harmonised System of Classification and Labelling of Chemicals, 5th revised edition 2013

HSNO means Hazardous Substances and New Organisms Act 1996

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