

Safety Data Sheet

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This Safety Data Sheet has been prepared in accordance with the SS586 Specification for Hazard Communication for Hazardous Chemicals and Dangerous Goods.

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SECTION 1: Identification

1.1. Product identifier

3MTM FiltekTM One Bulk Fill Restorative

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 Technologies (S) Pte Ltd, 10 Ang Mo Kio Street 65, Singapore 569059

Telephone: +65 6450 8888 **Website:** www.3m.com.sg

1.4. Emergency telephone number

+65 6591 6601 (8.15am - 5.00pm, Monday - Friday)

SECTION 2: Hazard identification

2.1. Classification of the substance or mixture

Skin Sensitizer: Category 1.

2.2. Label elements

SIGNAL WORD

WARNING!

Symbols

Exclamation mark |

Pictograms



HAZARD STATEMENTS

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3MTM FiltekTM One Bulk Fill Restorative

H317 May cause an allergic skin reaction.

PRECAUTIONARY STATEMENTS

Prevention:

P280E Wear protective gloves.

Response:

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

2.3. Other 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.

SECTION 3: Composition/information on ingredients

This material is a mixture.

Ingredient	CAS Nbr	% by Wt
Silane Treated Ceramic	444758-98-9	60 - 70
Aromatic Urethane Dimethacrylate	1431303-59-1	10 - 20
Diurethane Dimethacrylate (UDMA)	72869-86-4	1 - 10
Silane Treated Silica	248596-91-0	1 - 10
Ytterbium Fluoride (YbF3)	13760-80-0	1 - 10
1,12-Dodecane Dimethycrylate (DDDMA)	72829-09-5	< 10
Silane Treated Zirconia	None	< 5
Water	7732-18-5	< 5
N,N-DIMETHYLBENZOCAINE	10287-53-3	< 0.3

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> 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. 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 handle until all safety precautions have been read and understood. Do not breathe 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. 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. Use personal protective equipment (eg. gloves, respirators...) as required.

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.

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
Color	White
Odor	Slight Acrylate
Odour threshold	No data available.
pH	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	No data available.
Flammability	Not applicable.
Flammable Limits(LEL)	Not applicable.
Flammable Limits(UEL)	Not applicable.
Vapour pressure	Not applicable.
Vapor Density and/or Relative Vapor Density	Not applicable.
Density	1.9 g/cm3
Relative density	1.9 [Ref Std:WATER=1]
Water solubility	Negligible
Solubility- non-water	No data available.
Partition coefficient: n-octanol/water	No data available.
Autoignition temperature	No data available.
Decomposition temperature	No data available.
Kinematic Viscosity	No data available.
Molecular weight	Not applicable.

Particle Characteristics	Not applicable.
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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

3MTM FiltekTM One Bulk Fill Restorative

Stable.

10.3 Possibility of hazardous reactions

Hazardous polymerisation will not occur.

10.4 Conditions to avoid

Heat.

10.5 Incompatible materials

Strong oxidising agents.

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

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. May cause additional health effects (see below).

Additional Health Effects:

Reproductive/Developmental Toxicity:

Contains a chemical or chemicals which can cause birth defects or other reproductive harm.

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	Professio nal judgeme nt	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	Professio nal judgeme nt	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	Rat	LD50 > 2,000 mg/kg
Diurethane Dimethacrylate (UDMA)	Ingestion	Rat	LD50 > 5,000 mg/kg
Ytterbium Fluoride (YbF3)	Dermal	Professio nal judgeme nt	LD50 estimated to be > 5,000 mg/kg
Ytterbium Fluoride (YbF3)	Ingestion	Rat	LD50 > 5,000 mg/kg
1,12-Dodecane Dimethycrylate (DDDMA)	Dermal	similar compoun ds	LD50 > 2,000 mg/kg
1,12-Dodecane Dimethycrylate (DDDMA)	Ingestion	similar compoun ds	LD50 > 2,000 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
N,N-DIMETHYLBENZOCAINE	Dermal	Rat	LD50 > 2,000 mg/kg
N,N-DIMETHYLBENZOCAINE	Ingestion	Rat	LD50 > 2,000 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Silane Treated Ceramic	similar compoun ds	No significant irritation
Aromatic Urethane Dimethacrylate	In vitro data	No significant irritation
Silane Treated Zirconia	Rabbit	No significant irritation
Diurethane Dimethacrylate (UDMA)	Rabbit	No significant irritation
1,12-Dodecane Dimethycrylate (DDDMA)	similar compoun ds	No significant irritation
Silane Treated Silica	Professio nal judgemen t	No significant irritation
N,N-DIMETHYLBENZOCAINE	Rabbit	No significant irritation

Serious Eve Damage/Irritation

Name	Species	Value
Silane Treated Ceramic	similar compoun ds	Mild irritant
Aromatic Urethane Dimethacrylate	In vitro data	No significant irritation
Silane Treated Zirconia	Rabbit	Mild irritant

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Diurethane Dimethacrylate (UDMA)	Rabbit	No significant irritation
Ytterbium Fluoride (YbF3)	Professio	Mild irritant
	nal	
	judgemen	
	t	
1,12-Dodecane Dimethycrylate (DDDMA)	similar	Mild irritant
	compoun	
	ds	
Silane Treated Silica	Professio	No significant irritation
	nal	
	judgemen	
	t	
N,N-DIMETHYLBENZOCAINE	Rabbit	No significant irritation

Sensitization:

Skin Sensitisation

Name	Species	Value
Silane Treated Ceramic	similar compoun ds	Not classified
Aromatic Urethane Dimethacrylate	Professio nal judgemen t	Sensitising
Diurethane Dimethacrylate (UDMA)	Multiple animal species	Sensitising
1,12-Dodecane Dimethycrylate (DDDMA)	similar compoun ds	Sensitising
N,N-DIMETHYLBENZOCAINE		Not classified

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
Diurethane Dimethacrylate (UDMA)	In Vitro	Not mutagenic
1,12-Dodecane Dimethycrylate (DDDMA)	In Vitro	Not mutagenic
N,N-DIMETHYLBENZOCAINE	In vivo	Not mutagenic
N,N-DIMETHYLBENZOCAINE	In Vitro	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
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

Name	Route	Value	Species	Test result	Exposure
					Duration

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Diurethane Dimethacrylate (UDMA)	Ingestion	Not classified for female reproduction	Rat	NOAEL 1,000 mg/kg/day	premating into lactation
Diurethane Dimethacrylate (UDMA)	Ingestion	Not classified for male reproduction	Rat	NOAEL 1,000 mg/kg/day	56 days
Diurethane Dimethacrylate (UDMA)	Ingestion	Not classified for development	Rat	NOAEL 1,000 mg/kg/day	premating into lactation
N,N-DIMETHYLBENZOCAINE	Ingestion	Not classified for female reproduction	Rat	NOAEL 600 mg/kg/day	premating into lactation
N,N-DIMETHYLBENZOCAINE	Ingestion	Not classified for development	Rat	NOAEL 50 mg/kg/day	premating into lactation
N,N-DIMETHYLBENZOCAINE	Ingestion	Toxic to male reproduction	Rat	NOAEL 50 mg/kg/day	53 days

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	
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
Diurethane Dimethacrylate (UDMA)	Ingestion	liver kidney and/or bladder heart skin endocrine system gastrointestinal tract bone, teeth, nails, and/or hair hematopoietic system immune system muscles nervous system eyes respiratory system vascular system	Not classified	Rat	NOAEL 1,000 mg/kg/day	56 days
N,N- DIMETHYLBENZOCAI NE	Ingestion	hematopoietic system	Some positive data exist, but the data are not sufficient for classification	Rat	NOAEL 74 mg/kg/day	28 days
N,N- DIMETHYLBENZOCAI NE	Ingestion	liver heart endocrine system gastrointestinal tract bone, teeth, nails, and/or hair immune system muscles nervous system eyes kidney and/or bladder respiratory system vascular system	Not classified	Rat	NOAEL 900 mg/kg/day	28 days

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

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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

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 Nbr	Organism	Type	Exposure	Test endpoint	Test result
Silane Treated Ceramic	444758-98-9	N/A	Data not available or insufficient for classification	N/A	N/A	N/A
Aromatic Urethane Dimethacrylate	1431303-59-1	Green algae	Experimental	72 hours	ErC50	>100 mg/l
Aromatic Urethane Dimethacrylate	1431303-59-1	Water flea	Experimental	48 hours	EC50	>100 mg/l
Aromatic Urethane Dimethacrylate	1431303-59-1	Green algae	Experimental	72 hours	ErC10	>100 mg/l
Aromatic Urethane Dimethacrylate	1431303-59-1	Water flea	Experimental	21 days	NOEC	800 mg/l
1,12-Dodecane Dimethycrylate (DDDMA)	72829-09-5	Green algae	Experimental	72 hours	ErC50	0.017 mg/l
1,12-Dodecane Dimethycrylate (DDDMA)	72829-09-5	Water flea	Experimental	48 hours	EC50	>100 mg/l
1,12-Dodecane Dimethycrylate (DDDMA)	72829-09-5	Green algae	Experimental	72 hours	ErC10	0.0064 mg/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	N/A	Data not available or insufficient for classification	N/A	N/A	N/A
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	N/A	Data not available or insufficient for classification	N/A	N/A	N/A
N,N- DIMETHYLBENZ	10287-53-3	Activated sludge	Experimental	3 hours	EC50	>1,000 mg/l

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OCAINE						
N,N-	10287-53-3	Green algae	Experimental	72 hours	EL50	2.8 mg/l
DIMETHYLBENZ						
OCAINE						
N,N-	10287-53-3	Rainbow trout	Experimental	96 hours	LC50	1.9 mg/l
DIMETHYLBENZ						
OCAINE						
N,N-	10287-53-3	Water flea	Experimental	48 hours	EC50	4.5 mg/l
DIMETHYLBENZ						
OCAINE						
N,N-	10287-53-3	Green algae	Experimental	72 hours	ErC10	0.71 mg/l
DIMETHYLBENZ						
OCAINE						

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Silane Treated Ceramic	444758-98-9	Data not available-insufficient	N/A	N/A	N/A	N/A
Aromatic Urethane Dimethacrylate	1431303-59-1	Experimental Biodegradation	28 days	CO2 evolution	4.88 %CO2 evolution/THCO2 evolution	OECD 301B - Modified sturm or CO2
1,12-Dodecane Dimethycrylate (DDDMA)	72829-09-5	Experimental Biodegradation	28 days	CO2 evolution	97.3 %CO2 evolution/THCO2 evolution	OECD 301B - Modified sturm or CO2
Diurethane Dimethacrylate (UDMA)	72869-86-4	Experimental Biodegradation	28 days	CO2 evolution	22 %CO2 evolution/THCO2 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	N/A	N/A	N/A
Ytterbium Fluoride (YbF3)	13760-80-0	Data not available- insufficient	N/A	N/A	N/A	N/A
Silane Treated Zirconia	None	Data not available-insufficient	N/A	N/A	N/A	N/A
N,N- DIMETHYLBENZ OCAINE	10287-53-3	Experimental Biodegradation	28 days	CO2 evolution	40 %CO2 evolution/THCO2 evolution	OECD 301B - Modified sturm or CO2
N,N- DIMETHYLBENZ OCAINE	10287-53-3	Experimental Hydrolysis		Hydrolytic half-life (pH 7)	>1 years (t 1/2)	OECD 111 Hydrolysis func of pH

12.3 : Bioaccumulative potential

Material	CAS Nbr	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	Experimental Bioconcentration		Log Kow	6.9	OECD 117 log Kow HPLC method
1,12-Dodecane Dimethycrylate (DDDMA)	72829-09-5	Modeled Bioconcentration		Bioaccumulation factor	6.6	Catalogic™
1,12-Dodecane Dimethycrylate (DDDMA)	72829-09-5	Experimental Bioconcentration		Log Kow	>6.5	830.7570 Part. Coef by LC
Diurethane	72869-86-4	Experimental		Log Kow	3.39	

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Dimethacrylate (UDMA)		Bioconcentration				
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
N,N- DIMETHYLBENZ OCAINE	10287-53-3	Experimental Bioconcentration		Log Kow	3.2	OECD 117 log Kow HPLC method

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

International Regulations

UN No.: Not restricted for transport.

UN Proper shipping name: Not restricted for transport.

Transportation Class (IMO): None assigned Transportation Class (IATA): None assigned

Other Dangerous Goods Descriptions (IMO): None assigned Other Dangerous Goods Descriptions (IATA): None assigned

Packing Group: None assigned Marine pollutant: None assigned

SECTION 15: Regulatory information

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

Global inventory status

Contact 3M for more information.

This product may contain component(s) that are regulated by the following:

Workplace Safety and Health Act & Workplace Safety and Health (General Provisions) Regulations: this product is subject to SDS, labelling, PEL and other requirements in the Act/Regulations.

Fire Safety (Petroleum and Flammable Materials) Regulations: This product is subject to the requirements in the Regulations Environmental Protection and Management (Hazardous Substances) Regulations: This product is subject to the requirements in the Regulations

Health Product (Medical Devices) Regulations: This product is subject to the requirements of this regulation.

SECTION 16: Other information

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 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.

3M Singapore SDSs are available at www.3m.com.sg

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