SAFETY DATA SHEETS

This SDS packet was issued with item:

075022744

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

075022603

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

0750020750 075014907 075022611 075022629 075022637 075022645 075022652 075022660 075022678 075022686 075022694 075022702 075022710 075022728 075022736 075022751 075022769 075022777 075022785 075022918 075022926 075022934 075022942 075022959 075022967 075022975 075022991 075023007 075023015 075023031 075023049 075023056 075023064 075023072 075023213 075023239 075023262 075023288 075023296 075023304 075023312 075023320 075023346 075023353 075023361 075023379 075023395 075023403 075023411 075023429 075023437 075023510 075023528



Safety Data Sheet

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SECTION 1: Identification

1.1. Product identifier

3MTM FiltekTM Supreme Ultra Universal Restorative (6028, 6029, 5916)

1.2. Recommended use and restrictions on use

Recommended use

Dental Product, Restorative

Restrictions on use

For use only by dental professionals

1.3. Supplier's details

MANUFACTURER: 3M

DIVISION: Oral Care Solutions Division

ADDRESS: 3M Center, St. Paul, MN 55144-1000, USA

Telephone: 1-888-3M HELPS (1-888-364-3577)

1.4. Emergency telephone number

1-800-364-3577 or (651) 737-6501 (24 hours)

SECTION 2: Hazard identification

This document has been prepared in accordance with the U.S. OSHA Hazard Communication Standard, which requires the inclusion of all known hazards of the product or ingredients regardless of the potential risk. The risks of the hazards communicated in this document may vary depending on the potential for exposure.

2.1. Hazard classification

Skin Sensitizer: Category 1.

2.2. Label elements

Signal word

Warning

Symbols

Exclamation mark

Pictograms



Hazard Statements

May cause an allergic skin reaction.

Precautionary Statements

Prevention:

Avoid breathing dust/fume/gas/mist/vapors/spray.

Wear protective gloves.

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

Response:

IF ON SKIN: Wash with plenty of soap and water.

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

Wash contaminated clothing before reuse.

Disposal:

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

SECTION 3: Composition/information on ingredients

Ingredient	C.A.S. No.	% by Wt
Silane Treated Ceramic	444758-98-9	60 - 80 Trade Secret *
Bisphenol A Diglycidyl Ether Dimethacrylate (BISGMA)	1565-94-2	1 - 10 Trade Secret *
Bisphenol A Polyethylene Glycol Diether Dimethacrylate (BISEMA-6)	41637-38-1	1 - 10 Trade Secret *
Diurethane Dimethacrylate (UDMA)	72869-86-4	1 - 10 Trade Secret *
Silane Treated Silica	248596-91-0	1 - 10 Trade Secret *
Polyethylene Glycol Dimethacrylate (PEGDMA)	25852-47-5	< 5 Trade Secret *
Silane Treated Zirconia	None	1 - 5 Trade Secret *
Triethylene glycol dimethacrylate	109-16-0	< 1 Trade Secret *
Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	162881-26-7	< 0.05 Trade Secret *

^{*}The specific chemical identity and/or exact percentage (concentration) of this composition has been withheld as a trade secret.

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

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/vapors/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. Avoid contact with oxidizing 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 oxidizing 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 SDS.

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

Appearance

Physical stateSolidColorTooth

Specific Physical Form: Paste

Odor Slight Acrylate **Odor threshold** No Data Available Not Applicable pΗ **Melting point** No Data Available **Boiling Point** 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 Not Applicable **Vapor Pressure Vapor Density** Not Applicable **Density** 1.9 g/cm3

Specific Gravity 1.9 [Ref Std:WATER=1]

Solubility In Water

Solubility - non-water

No Data Available
Partition coefficient: n-octanol/ water

Autoignition temperature

No Data Available
No Data Available
No Data Available
No Data Available

ViscosityNo Data AvailableMolecular weightNo Data AvailableVolatile Organic CompoundsNot ApplicableVOC Less H2O & Exempt SolventsNot Applicable

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 polymerization will not occur.

10.4. Conditions to avoid

Heat

10.5. Incompatible materials

Strong oxidizing agents

10.6. Hazardous decomposition products

Substance

None known.

Condition

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 labeling, an ingredient may not be available for exposure, or the data may not be relevant to the material as a whole.

This document has been prepared in accordance with the U.S. OSHA Hazard Communication Standard, which requires the inclusion of all known hazards of the product or ingredients regardless of the potential risk. The risks of the hazards communicated in this document may vary depending on the potential for exposure. The information below represents toxicological information associated with the individual components of the uncured product. Once properly mixed and/or cured, the product is safe for its intended use.

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:

May be harmful if swallowed.

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

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 Ceramic	Dermal		LD50 estimated to be > 5,000 mg/kg
Silane Treated Ceramic	Ingestion		LD50 estimated to be 2,000 - 5,000 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
Diurethane Dimethacrylate (UDMA)	Dermal	Professio nal judgeme nt	LD50 estimated to be > 5,000 mg/kg
Bisphenol A Polyethylene Glycol Diether Dimethacrylate (BISEMA-6)	Dermal	Rat	LD50 > 2,000 mg/kg
Bisphenol A Polyethylene Glycol Diether Dimethacrylate (BISEMA-6)	Ingestion	Rat	LD50 > 35,000 mg/kg
Diurethane Dimethacrylate (UDMA)	Ingestion	Rat	LD50 > 5,000 mg/kg
Bisphenol A Diglycidyl Ether Dimethacrylate (BISGMA)	Dermal	Professio nal judgeme nt	LD50 estimated to be > 5,000 mg/kg
Bisphenol A Diglycidyl Ether Dimethacrylate (BISGMA)	Ingestion	Rat	LD50 > 11,700 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
Polyethylene Glycol Dimethacrylate (PEGDMA)	Dermal	Rabbit	LD50 15,500 mg/kg
Polyethylene Glycol Dimethacrylate (PEGDMA)	Ingestion	Rat	LD50 9,400 mg/kg
Triethylene glycol dimethacrylate	Dermal	Professio nal judgeme nt	LD50 estimated to be > 5,000 mg/kg
Triethylene glycol dimethacrylate	Ingestion	Rat	LD50 10,837 mg/kg
Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	Dermal	Rat	LD50 > 2,000 mg/kg
Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	Ingestion	Rat	LD50 > 2,000 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Silane Treated Ceramic	similar	No significant irritation
	compoun	
	ds	
Silane Treated Silica	Professio	No significant irritation
	nal	
	judgeme	
	nt	
Bisphenol A Polyethylene Glycol Diether Dimethacrylate (BISEMA-6)	Rabbit	Minimal irritation
Bisphenol A Diglycidyl Ether Dimethacrylate (BISGMA)	Rabbit	No significant irritation
Silane Treated Zirconia	Rabbit	No significant irritation

Polyethylene Glycol Dimethacrylate (PEGDMA)	Rabbit	Mild irritant
Triethylene glycol dimethacrylate	Guinea	Mild irritant
	pig	
Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	Rabbit	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
Silane Treated Ceramic	similar compoun ds	Mild irritant
Silane Treated Silica	Professio nal judgeme nt	No significant irritation
Bisphenol A Polyethylene Glycol Diether Dimethacrylate (BISEMA-6)	Rabbit	No significant irritation
Bisphenol A Diglycidyl Ether Dimethacrylate (BISGMA)	In vitro data	No significant irritation
Silane Treated Zirconia	Rabbit	Mild irritant
Polyethylene Glycol Dimethacrylate (PEGDMA)	Rabbit	Moderate irritant
Triethylene glycol dimethacrylate	Professio nal judgeme nt	Moderate irritant
Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	Rabbit	No significant irritation

Skin Sensitization

Name	Species	Value
Silane Treated Ceramic	similar	Not classified
	compoun	
	ds	
Bisphenol A Polyethylene Glycol Diether Dimethacrylate (BISEMA-6)	Guinea	Not classified
	pig	
Diurethane Dimethacrylate (UDMA)	Guinea	Sensitizing
	pig	_
Bisphenol A Diglycidyl Ether Dimethacrylate (BISGMA)	Mouse	Not classified
Polyethylene Glycol Dimethacrylate (PEGDMA)	Guinea	Not classified
	pig	
Triethylene glycol dimethacrylate	Human	Sensitizing
	and	
	animal	
Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	Guinea	Sensitizing
-	pig	

Respiratory Sensitization

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

Germ Cell Mutagenicity

Germ Gen Mutagementy		
Name	Route	Value
Bisphenol A Polyethylene Glycol Diether Dimethacrylate (BISEMA-6)	In Vitro	Not mutagenic
Bisphenol A Diglycidyl Ether Dimethacrylate (BISGMA)	In Vitro	Not mutagenic
Silane Treated Zirconia	In Vitro	Some positive data exist, but the data are not
		sufficient for classification
Triethylene glycol dimethacrylate	In Vitro	Some positive data exist, but the data are not
		sufficient for classification
Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	In Vitro	Not mutagenic

Carcinogenicity

Name	Route	Species	Value
Silane Treated Ceramic	Inhalation	similar	Some positive data exist, but the data are not
		compoun	sufficient for classification
		ds	

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Silane Treated Zirconia	Inhalation	animal	Some positive data exist, but the data are not sufficient for classification	
		species		ı
Triethylene glycol dimethacrylate	Dermal	Mouse	Not carcinogenic	1

Reproductive Toxicity

Reproductive and/or Developmental Effects

Name	Route	Value	Species	Test Result	Exposure Duration
Bisphenol A Diglycidyl Ether Dimethacrylate (BISGMA)	Ingestion	Not classified for development	Rat	NOAEL 1,000 mg/kg/day	during gestation
Triethylene glycol dimethacrylate	Ingestion	Not classified for female reproduction	Mouse	NOAEL 1 mg/kg/day	1 generation
Triethylene glycol dimethacrylate	Ingestion	Not classified for male reproduction	Mouse	NOAEL 1 mg/kg/day	1 generation
Triethylene glycol dimethacrylate	Ingestion	Not classified for development	Mouse	NOAEL 1 mg/kg/day	1 generation

Target Organ(s)

Specific Target Organ Toxicity - single exposure

Specific zurger organ	steme ranger organ romerty single enposters								
Name	Route	Target Organ(s)	Value	Species	Test Result	Exposure Duration			
Polyethylene Glycol	Inhalation	respiratory irritation	Some positive data exist, but the	similar	NOAEL Not				
Dimethacrylate			data are not sufficient for	health	available				
(PEGDMA)			classification	hazards					

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	
Bisphenol A Diglycidyl Ether Dimethacrylate (BISGMA)	Ingestion	endocrine system hematopoietic system liver heart skin 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 1,000 mg/kg/day	90 days
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
Triethylene glycol dimethacrylate	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.

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Ecotoxicological information

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

Chemical fate information

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

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.

EPA Hazardous Waste Number (RCRA): Not regulated

SECTION 14: Transport Information

For Transport Information, please visit http://3M.com/Transportinfo or call 1-800-364-3577 or 651-737-6501.

SECTION 15: Regulatory information

15.1. US Federal Regulations

Contact 3M for more information.

EPCRA 311/312 Hazard Classifications:

Physical Hazards	
Not applicable	

Health Hazards

Respiratory or Skin Sensitization

Additional TSCA Information

Components	CAS No	Additional Information
Silane Treated Silica	248596-91-0	Allowed use(s): Coating additive.

15.2. State Regulations

Contact 3M for more information.

15.3. Chemical Inventories

This material contains one or more substances not listed on the TSCA Inventory. Commercial use of this material is regulated by the FDA.

Contact 3M for more information.

15.4. International Regulations

Contact 3M for more information.

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This SDS has been prepared to meet the U.S. OSHA Hazard Communication Standard, 29 CFR 1910.1200.

SECTION 16: Other information

NFPA Hazard Classification

Health: 2 Flammability: 1 Instability: 0 Special Hazards: None

National Fire Protection Association (NFPA) hazard ratings are designed for use by emergency response personnel to address the hazards that are presented by short-term, acute exposure to a material under conditions of fire, spill, or similar emergencies. Hazard ratings are primarily based on the inherent physical and toxic properties of the material but also include the toxic properties of combustion or decomposition products that are known to be generated in significant quantities.

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