Safety Data Sheet

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SECTION 1: Identification

1.1. Product identifier
3M™ Filtek™ 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

Substance	Condition
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
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 state	Solid
Color	Tooth
Specific Physical Form:	Paste
Odor	Slight Acrylate
Odor threshold	*No Data Available*
pH	*Not Applicable*
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*
Vapor Pressure	*Not Applicable*
Vapor Density	*Not Applicable*
Density	1.9 g/cm3
Specific Gravity	1.9 [*Ref Std:*WATER=1]
Solubility In Water	*No Data Available*
Solubility- non-water	*No Data Available*
Partition coefficient: n-octanol/ water	*Not Applicable*
Autoignition temperature	*No Data Available*
Decomposition temperature	*No Data Available*

Viscosity	*No Data Available*
Molecular weight	*No Data Available*
Volatile Organic Compounds	*Not Applicable*
VOC Less H2O & Exempt Solvents	*Not 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	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 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	Professional judgement	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	Professional judgement	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	Professional judgement	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 compounds	No significant irritation
Silane Treated Silica	Professional judgement	No significant irritation
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 pig	Mild irritant
Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	Rabbit	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
Silane Treated Ceramic	similar compounds	Mild irritant
Silane Treated Silica	Professional judgement	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	Professional judgement	Moderate irritant
Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	Rabbit	No significant irritation

Skin Sensitization

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

Respiratory Sensitization

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

Germ Cell Mutagenicity

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 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
Triethylene glycol dimethacrylate	Dermal	Mouse	Not carcinogenic

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

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

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	
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.

SECTION 12: Ecological information

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.

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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