



Safety Data Sheet

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SECTION 1: Identification

1.1. Product identifier

6028/ 6029/ 5916 3M™ ESPE™ FILTEK™ SUPREME ULTRA UNIVERSAL RESTORATIVE

Composite

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 1B.

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.

2.3. Hazards not otherwise classified

None.

SECTION 3: Composition/information on ingredients

Ingredient	C.A.S. No.	% by Wt
SILANE TREATED CERAMIC	444758-98-9	60 - 80 Trade Secret *
SILANE TREATED SILICA	248596-91-0	1 - 10 Trade Secret *
DIURETHANE DIMETHACRYLATE (UDMA)	72869-86-4	1 - 10 Trade Secret *
BISPHENOL A POLYETHYLENE GLYCOL DIETHER DIMETHACRYLATE	41637-38-1	1 - 10 Trade Secret *
BISPHENOL A DIGLYCIDYL ETHER DIMETHACRYLATE (BISGMA)	1565-94-2	1 - 10 Trade Secret *
SILANE TREATED ZIRCONIA	Unknown	1 - 10 Trade Secret *
POLYETHYLENE GLYCOL DIMETHACRYLATE	25852-47-5	< 5 Trade Secret *
TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA)	109-16-0	< 5 Trade Secret *
2,6-DI-TERT-BUTYL-P-CRESOL	128-37-0	< 0.5 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

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**Substance**

Carbon monoxide

Carbon dioxide

Condition

During Combustion

During Combustion

5.3. Special protective actions for fire-fighters

No special protective actions for fire-fighters are anticipated.

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.

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.

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. Avoid breathing dust/fume/gas/mist/vapors/spray. Do not get in eyes, on skin, or on clothing. 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.)

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

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	C.A.S. No.	Agency	Limit type	Additional Comments
2,6-DI-TERT-BUTYL-P-CRESOL	128-37-0	ACGIH	TWA(inhalable fraction and vapor):2 mg/m3	A4: Not class. as human carcin

ACGIH : American Conference of Governmental Industrial Hygienists

AIHA : American Industrial Hygiene Association

CMRG : Chemical Manufacturer's Recommended Guidelines

OSHA : United States Department of Labor - Occupational Safety and Health Administration

TWA: Time-Weighted-Average

STEL: Short Term Exposure Limit

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

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

General Physical Form:	Solid
Specific Physical Form:	Paste
Odor, Color, Grade:	Slight acrylate odor, Tooth colored.
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)	<i>Not Applicable</i>
Flammable Limits(UEL)	<i>Not Applicable</i>
Vapor Pressure	<i>Not Applicable</i>
Vapor Density	<i>Not Applicable</i>
Density	1.9 g/cm3
Specific Gravity	1.9 [Ref Std: WATER=1]
Solubility In Water	<i>No Data Available</i>
Solubility- non-water	<i>No Data Available</i>
Partition coefficient: n-octanol/ water	<i>Not Applicable</i>
Autoignition temperature	<i>No Data Available</i>
Decomposition temperature	<i>No Data Available</i>
Viscosity	<i>No Data Available</i>
Molecular weight	<i>No Data Available</i>
Volatile Organic Compounds	<i>Not Applicable</i>
VOC Less H2O & Exempt Solvents	<i>Not Applicable</i>

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

<u>Substance</u>	<u>Condition</u>
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
BISPHENOL A POLYETHYLENE GLYCOL DIETHER DIMETHACRYLATE	Dermal	Professional judgment	LD50 estimated to be > 5,000 mg/kg
DIURETHANE DIMETHACRYLATE (UDMA)	Dermal	Professional judgment	LD50 estimated to be > 5,000 mg/kg
BISPHENOL A POLYETHYLENE GLYCOL DIETHER DIMETHACRYLATE	Ingestion	Rat	LD50 > 2,000 mg/kg
DIURETHANE DIMETHACRYLATE (UDMA)	Ingestion	Rat	LD50 > 5,000 mg/kg
BISPHENOL A DIGLYCIDYL ETHER DIMETHACRYLATE (BISGMA)	Ingestion		LD50 estimated to be 2,000 - 5,000 mg/kg
BISPHENOL A DIGLYCIDYL ETHER DIMETHACRYLATE (BISGMA)	Dermal	Professional judgment	LD50 estimated to be 2,000 - 5,000 mg/kg
POLYETHYLENE GLYCOL DIMETHACRYLATE	Dermal		LD50 estimated to be > 5,000 mg/kg
POLYETHYLENE GLYCOL DIMETHACRYLATE	Ingestion	Rat	LD50 > 5,000 mg/kg
TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA)	Dermal	Professional judgment	LD50 estimated to be > 5,000 mg/kg
TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA)	Ingestion	Rat	LD50 10,837 mg/kg
2,6-DI-TERT-BUTYL-P-CRESOL	Dermal	Rat	LD50 > 2,000 mg/kg
2,6-DI-TERT-BUTYL-P-CRESOL	Ingestion	Rat	LD50 > 2,930 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 DIGLYCIDYL ETHER DIMETHACRYLATE (BISGMA)	Not available	Minimal irritation
TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA)	Guinea pig	Mild irritant
2,6-DI-TERT-BUTYL-P-CRESOL	Human and animal	Minimal 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 DIGLYCIDYL ETHER DIMETHACRYLATE (BISGMA)	Not available	Moderate irritant
TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA)	Professional judgement	Moderate irritant
2,6-DI-TERT-BUTYL-P-CRESOL	Rabbit	Mild irritant

Skin Sensitization

Name	Species	Value
SILANE TREATED CERAMIC	similar compounds	Some positive data exist, but the data are not sufficient for classification
BISPHENOL A POLYETHYLENE GLYCOL DIETHER DIMETHACRYLATE	Guinea pig	Not sensitizing
BISPHENOL A DIGLYCIDYL ETHER DIMETHACRYLATE (BISGMA)	Guinea pig	Sensitizing
TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA)	Human and animal	Sensitizing
2,6-DI-TERT-BUTYL-P-CRESOL	Human	Some positive data exist, but the data are not sufficient for classification

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	In Vitro	Not mutagenic
BISPHENOL A DIGLYCIDYL ETHER DIMETHACRYLATE (BISGMA)	In Vitro	Some positive data exist, but the data are not sufficient for classification
TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA)	In Vitro	Some positive data exist, but the data are not sufficient for classification

2,6-DI-TERT-BUTYL-P-CRESOL	In Vitro	Not mutagenic
2,6-DI-TERT-BUTYL-P-CRESOL	In vivo	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
TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA)	Dermal	Mouse	Not carcinogenic
2,6-DI-TERT-BUTYL-P-CRESOL	Ingestion	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
BISPHENOL A DIGLYCIDYL ETHER DIMETHACRYLATE (BISGMA)	Ingestion	Not toxic to female reproduction	Mouse	NOAEL 0.8 mg/kg/day	prematuring & during gestation
BISPHENOL A DIGLYCIDYL ETHER DIMETHACRYLATE (BISGMA)	Ingestion	Not toxic to male reproduction	Mouse	NOAEL 0.8 mg/kg/day	prematuring & during gestation
BISPHENOL A DIGLYCIDYL ETHER DIMETHACRYLATE (BISGMA)	Ingestion	Not toxic to development	Mouse	NOAEL 0.8 mg/kg/day	prematuring & during gestation
TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA)	Ingestion	Not toxic to female reproduction	Mouse	NOAEL 1 mg/kg/day	1 generation
TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA)	Ingestion	Not toxic to male reproduction	Mouse	NOAEL 1 mg/kg/day	1 generation
TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA)	Ingestion	Not toxic to development	Mouse	NOAEL 1 mg/kg/day	1 generation
2,6-DI-TERT-BUTYL-P-CRESOL	Ingestion	Not toxic to female reproduction	Rat	NOAEL 500 mg/kg/day	2 generation
2,6-DI-TERT-BUTYL-P-CRESOL	Ingestion	Not toxic to male reproduction	Rat	NOAEL 500 mg/kg/day	2 generation
2,6-DI-TERT-BUTYL-P-CRESOL	Ingestion	Some positive developmental data exist, but the data are not sufficient for classification	Rat	NOAEL 100 mg/kg/day	2 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	Some positive data exist, but the data are not sufficient for classification	similar compounds	NOAEL Not available	
BISPHENOL A DIGLYCIDYL ETHER DIMETHACRYLATE (BISGMA)	Ingestion	endocrine system liver nervous system kidney and/or bladder	All data are negative	Mouse	NOAEL 0.8 mg/kg/day	prematuring & during gestation
TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA)	Dermal	kidney and/or bladder	Some positive data exist, but the data are not sufficient for classification	Mouse	NOAEL 833 mg/kg/day	78 weeks
TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA)	Dermal	blood	All data are negative	Mouse	NOAEL 833 mg/kg/day	78 weeks
2,6-DI-TERT-BUTYL-P-	Ingestion	liver	Some positive data exist, but the	Rat	NOAEL 250	28 days

CRESOL			data are not sufficient for classification		mg/kg/day	
2,6-DI-TERT-BUTYL-P-CRESOL	Ingestion	kidney and/or bladder	Some positive data exist, but the data are not sufficient for classification	Rat	NOAEL 500 mg/kg/day	2 generation
2,6-DI-TERT-BUTYL-P-CRESOL	Ingestion	blood	Some positive data exist, but the data are not sufficient for classification	Rat	LOAEL 420 mg/kg/day	40 days
2,6-DI-TERT-BUTYL-P-CRESOL	Ingestion	endocrine system	Some positive data exist, but the data are not sufficient for classification	Rat	NOAEL 25 mg/kg/day	2 generation
2,6-DI-TERT-BUTYL-P-CRESOL	Ingestion	heart	Some positive data exist, but the data are not sufficient for classification	Mouse	NOAEL 3,480 mg/kg/day	10 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.

311/312 Hazard Categories:

Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No Immediate Hazard - Yes Delayed Hazard - No

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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