



Safety Data Sheet

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SECTION 1: Identification

1.1. Product identifier

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

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 * |
| 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 | None | 1 - 5 Trade Secret * |
| POLYETHYLENE GLYCOL DIMETHACRYLATE | 25852-47-5 | < 5 Trade Secret * |
| Triethylene glycol dimethacrylate | 109-16-0 | < 1 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. 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. 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. Avoid release to the environment. 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**

| | |
|--|-------------------------------------|
| General Physical Form: | Solid |
| Specific Physical Form: | Paste |
| Odor, Color, Grade: | Slight acrylate odor, Tooth colored |
| Odor threshold | <i>No Data Available</i> |
| pH | <i>Not Applicable</i> |
| Melting point | <i>No Data Available</i> |
| Boiling Point | <i>Not Applicable</i> |
| Flash Point | No flash point |
| Evaporation rate | <i>Not Applicable</i> |
| 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/cm ³ |
| 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 | Dermal | | No data available; calculated ATE >5,000 mg/kg |
| 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 |
| 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 | Dermal | | LD50 estimated to be > 5,000 mg/kg |
| POLYETHYLENE GLYCOL DIMETHACRYLATE | Ingestion | Rat | LD50 > 5,000 mg/kg |
| Triethylene glycol dimethacrylate | Dermal | Professional judgment | LD50 estimated to be > 5,000 mg/kg |
| Triethylene glycol dimethacrylate | Ingestion | Rat | LD50 10,837 mg/kg |

ATE = acute toxicity estimate

Skin Corrosion/Irritation

| Name | Species | Value |
|------------------------|-----------------------|---------------------------|
| SILANE TREATED CERAMIC | similar compounds | No significant irritation |
| SILANE TREATED SILICA | Professional judgment | No significant irritation |

| | | |
|--|---------------|---------------------------|
| | nt | |
| BISPHENOL A DIGLYCIDYL ETHER DIMETHACRYLATE (BISGMA) | Not available | Minimal irritation |
| SILANE TREATED ZIRCONIA | Rabbit | No significant irritation |
| Triethylene glycol dimethacrylate | Guinea pig | Mild irritant |

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 |
| SILANE TREATED ZIRCONIA | Rabbit | Mild irritant |
| Triethylene glycol dimethacrylate | Professional judgement | Moderate irritant |

Skin Sensitization

| Name | Species | Value |
|--|-------------------|----------------|
| SILANE TREATED CERAMIC | similar compounds | Not classified |
| BISPHENOL A POLYETHYLENE GLYCOL DIETHER DIMETHACRYLATE | Guinea pig | Not classified |
| DIURETHANE DIMETHACRYLATE (UDMA) | Guinea pig | Sensitizing |
| BISPHENOL A DIGLYCIDYL ETHER DIMETHACRYLATE (BISGMA) | Guinea pig | Sensitizing |
| Triethylene glycol dimethacrylate | Human and animal | 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 | In Vitro | Not mutagenic |
| BISPHENOL A DIGLYCIDYL ETHER DIMETHACRYLATE (BISGMA) | In Vitro | Some positive data exist, but the data are not sufficient for classification |
| 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 |

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 female reproduction | Mouse | NOAEL 0.8 mg/kg/day | prematuring & during gestation |
| BISPHENOL A DIGLYCIDYL ETHER DIMETHACRYLATE (BISGMA) | Ingestion | Not classified for male reproduction | Mouse | NOAEL 0.8 mg/kg/day | prematuring & during gestation |
| BISPHENOL A DIGLYCIDYL ETHER DIMETHACRYLATE (BISGMA) | Ingestion | Not classified for development | Mouse | NOAEL 0.8 mg/kg/day | prematuring & 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**

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 compounds | NOAEL Not available | |
| BISPHENOL A DIGLYCIDYL ETHER DIMETHACRYLATE (BISGMA) | Ingestion | endocrine system liver nervous system kidney and/or bladder | Not classified | Mouse | NOAEL 0.8 mg/kg/day | prematuring & during gestation |
| 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

| <u>Components</u> | <u>CAS No</u> | <u>Consent Order/SNUR</u> |
|-----------------------|---------------|-----------------------------------|
| SILANE TREATED SILICA | 248596-91-0 | Allowed use(s): Coating additive. |

15.2. State Regulations

Contact 3M for more information.

California Proposition 65**Ingredient**

Toluene

C.A.S. No.

108-88-3

Classification

Developmental Toxin

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

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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