

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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|------------------------|-----------|-------------------------|----------|
| Document Group: | 26-5783-1 | Version Number: | 5.00 |
| Issue Date: | 02/25/16 | Supersedes Date: | 10/24/14 |

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 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 | <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 H ₂ O & 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.

| | | | |
|------------------------|-----------|-------------------------|----------|
| Document Group: | 26-5783-1 | Version Number: | 5.00 |
| Issue Date: | 02/25/16 | Supersedes Date: | 10/24/14 |

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