



Safety Data Sheet

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SECTION 1: Identification

1.1. Product identifier

3M™ ESPE™ FILTEK™ SUPREME UNIVERSAL RESTORATIVE

Product Identification Numbers

70-2010-3469-4, 70-2010-3614-5, 70-2010-3615-2, 70-2010-3616-0, 70-2010-3617-8, 70-2010-3618-6, 70-2010-3619-4, 70-2010-3620-2, 70-2010-3621-0, 70-2010-3622-8, 70-2010-3623-6, 70-2010-3624-4

1.2. Recommended use and restrictions on use

Recommended use

Dental product, Composite restorative material

Restrictions on use

For use by dental professionals

1.3. Supplier's details

MANUFACTURER:	3M
DIVISION:	3M ESPE Dental Products
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

Acute Toxicity (oral): Category 4.

Skin Sensitizer: Category 1B.

2.2. Label elements

Signal word

Warning

Symbols

Exclamation mark |

Pictograms



Hazard Statements

Harmful if swallowed.

May cause an allergic skin reaction.

Precautionary Statements

Prevention:

Wear protective gloves.

Do not eat, drink or smoke when using this product.

Wash thoroughly after handling.

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.

Rinse mouth.

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

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	65 - 75 Trade Secret *
SILANE TREATED SILICA	248596-91-0	5 - 15 Trade Secret *
BISPHENOL A POLYETHYLENE GLYCOL DIETHER DIMETHACRYLATE (BISEMA6)	41637-38-1	5 - 15 Trade Secret *
DIURETHANE DIMETHACRYLATE (UDMA)	72869-86-4	5 - 15 Trade Secret *
BISPHENOL A DIGLYCIDYL ETHER METHACRYLATE (BISGMA)	1565-94-2	1 - 10 Trade Secret *
TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA)	109-16-0	< 5 Trade Secret *
BENZOTRIAZOL	96478-09-0	< 0.5
ETHYL 4-DIMETHYL AMINO BENZOATE (EDMAB)	10287-53-3	< 0.5
DIPHENYLIODONIUM HEXAFLUOROPHOSPHATE	58109-40-3	< 0.5

*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

Ventilate the area with fresh air. 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.

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. 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. Avoid release to the environment. Wash contaminated clothing before reuse.

7.2. Conditions for safe storage including any incompatibilities

No special storage requirements.

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. Use general dilution ventilation and/or local exhaust ventilation to control airborne exposures to below relevant Exposure Limits and/or control dust/fume/gas/mist/vapors/spray. If ventilation is not adequate, use respiratory protection equipment.

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/cm ³
Specific Gravity	1.9 [Ref Std: WATER=1]
Solubility in Water	Negligible
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>Not Applicable</i>
Volatile Organic Compounds	<i>Not Applicable</i>
Percent volatile	<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 may be reactive with certain agents under certain conditions - see the remaining headings in this section.

10.2. Chemical stability

Stable.

10.3. Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.4. Conditions to avoid

Light

10.5. Incompatible materials

None known.

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:

This product may have a characteristic odor; however, no adverse health effects are anticipated.

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:

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 300 - 2,000 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 (BISMA6)	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
BISPHENOL A POLYETHYLENE GLYCOL DIETHER DIMETHACRYLATE (BISMA6)	Ingestion	Rat	LD50 > 2,000 mg/kg
DIURETHANE DIMETHACRYLATE (UDMA)	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
DIURETHANE DIMETHACRYLATE (UDMA)	Ingestion	Rat	LD50 > 5,000 mg/kg
BISPHENOL A DIGLYCIDYL ETHER METHACRYLATE (BISGMA)	Ingestion		LD50 estimated to be 2,000 - 5,000 mg/kg
BISPHENOL A DIGLYCIDYL ETHER METHACRYLATE (BISGMA)	Dermal	Professional judgement	LD50 estimated to be 2,000 - 5,000 mg/kg
TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA)	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA)	Ingestion	Rat	LD50 10,837 mg/kg
ETHYL 4-DIMETHYL AMINO BENZOATE (EDMAB)	Dermal	Rat	LD50 > 2,000 mg/kg
ETHYL 4-DIMETHYL AMINO BENZOATE (EDMAB)	Ingestion	Rat	LD50 > 2,000 mg/kg
DIPHENYLIODONIUM HEXAFLUOROPHOSPHATE	Ingestion	Rat	LD50 32 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
SILANE TREATED CERAMIC	similar	No significant irritation

	compounds	
SILANE TREATED SILICA		No significant irritation
BISPHENOL A DIGLYCIDYL ETHER METHACRYLATE (BISGMA)	Not available	Minimal irritation
TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA)	Guinea pig	Mild irritant
ETHYL 4-DIMETHYL AMINO BENZOATE (EDMAB)	Rabbit	No significant irritation
DIPHENYLIODONIUM HEXAFLUOROPHOSPHATE	Rabbit	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
SILANE TREATED CERAMIC	similar compounds	Mild irritant
SILANE TREATED SILICA		No significant irritation
BISPHENOL A DIGLYCIDYL ETHER METHACRYLATE (BISGMA)	Not available	Moderate irritant
TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA)	Professional judgement	Moderate irritant
ETHYL 4-DIMETHYL AMINO BENZOATE (EDMAB)	Rabbit	Mild irritant
DIPHENYLIODONIUM HEXAFLUOROPHOSPHATE	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 (BISEMA6)	Guinea pig	Not sensitizing
BISPHENOL A DIGLYCIDYL ETHER METHACRYLATE (BISGMA)	Guinea pig	Sensitizing
TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA)	Human and animal	Sensitizing

Respiratory Sensitization

Name	Species	Value
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Germ Cell Mutagenicity

Name	Route	Value
BISPHENOL A POLYETHYLENE GLYCOL DIETHER DIMETHACRYLATE (BISEMA6)	In Vitro	Not mutagenic
BISPHENOL A DIGLYCIDYL ETHER METHACRYLATE (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
DIPHENYLIODONIUM HEXAFLUOROPHOSPHATE	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
TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA)	Dermal	Mouse	Not carcinogenic

Reproductive Toxicity**Reproductive and/or Developmental Effects**

Name	Route	Value	Species	Test Result	Exposure Duration
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BISPHENOL A DIGLYCIDYL ETHER METHACRYLATE (BISGMA)	Ingestion	Not toxic to female reproduction	Mouse	NOAEL 0.8 mg/kg/day	premating & during gestation
BISPHENOL A DIGLYCIDYL ETHER METHACRYLATE (BISGMA)	Ingestion	Not toxic to male reproduction	Mouse	NOAEL 0.8 mg/kg/day	premating & during gestation
BISPHENOL A DIGLYCIDYL ETHER METHACRYLATE (BISGMA)	Ingestion	Not toxic to development	Mouse	NOAEL 0.8 mg/kg/day	premating & 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

Target Organ(s)**Specific Target Organ Toxicity - single exposure**

Name	Route	Target Organ(s)	Value	Species	Test Result	Exposure Duration
DIPHENYLIODONIUM HEXAFLUOROPHOSPHATE	Inhalation	respiratory irritation	Some positive data exist, but the data are not sufficient for classification	Not available	Irritation Equivocal	

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 METHACRYLATE (BISGMA)	Ingestion	endocrine system liver nervous system kidney and/or bladder	All data are negative	Mouse	NOAEL 0.8 mg/kg/day	premating & 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

Aspiration Hazard

Name	Value
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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.

Incinerate uncured product in a permitted waste incineration facility. As a disposal alternative, utilize an acceptable permitted waste disposal facility.

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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