Safety Data Sheet

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SECTION 1: Identification

1.1. Product identifier
3M™ ESPE™ FILTEK™ BULK FILL POSTERIOR 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:	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
Skin Sensitizer: Category 1.

2.2. Label elements
Signal word
Warning

Symbols
Exclamation mark |

Pictograms

~Verified on 2014-08 by Henry Schein to be the most current version of the SDS. To be verified again on 2017-08. ~

Hazard Statements
May cause an allergic skin reaction.

Precautionary Statements

Prevention:
Avoid breathing dust/fume/gas/mist/vapors/spray.
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.

31% of the mixture consists of ingredients of unknown acute oral toxicity.

SECTION 3: Composition/information on ingredients

Ingredient	C.A.S. No.	% by Wt
SILANE TREATED CERAMIC	444758-98-9	60 - 70 Trade Secret *
AROMATIC URETHANE DIMETHACRYLATE	1431303-59-1	10 - 20 Trade Secret *
YTTERBIUM FLUORIDE (YbF3)	13760-80-0	1 - 10 Trade Secret *
DIURETHANE DIMETHACRYLATE (UDMA)	72869-86-4	1 - 10 Trade Secret *
SILANE TREATED SILICA	248596-91-0	1 - 10 Trade Secret *
1,12-DODECANE DIMETHYCRYLATE (DDDMA)	72829-09-5	< 5 Trade Secret *
SILANE TREATED ZIRCONIA	Unknown	< 5 Trade Secret *
WATER	7732-18-5	< 5 Trade Secret *
Pentanedioic acid, 2,2-dimethyl-4-methylene-, reaction products with glycidyl methacrylate	1429648-13-4	< 1 Trade Secret *
ETHYL 4-DIMETHYL AMINOBENZOATE (EDMAB)	10287-53-3	< 0.5 Trade Secret *
BENZOTRIAZOL	96478-09-0	< 0.5 Trade Secret *
Titanium Dioxide	13463-67-7	< 0.2 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	Condition
Carbon monoxide	During Combustion
Carbon dioxide	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
Contain spill. 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. Avoid release to the environment. 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

Ingredient	C.A.S. No.	Agency	Limit type	Additional Comments
Titanium Dioxide	13463-67-7	ACGIH	TWA:10 mg/m3	A4: Not class. as human carcin
Titanium Dioxide	13463-67-7	CMRG	TWA(as respirable dust):5 mg/m3	
Titanium Dioxide	13463-67-7	OSHA	TWA(as total dust):15 mg/m3	
FLUORIDES	13760-80-0	ACGIH	TWA(as F):2.5 mg/m3	A4: Not class. as human carcin
FLUORIDES	13760-80-0	OSHA	TWA(as dust):2.5 mg/m3;TWA(as F):2.5 mg/m3	

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 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

Under normal use conditions, airborne exposures are not expected to be significant enough to require respiratory protection.

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)	*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	Negligible
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*

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
Heat
High shear and high temperature conditions

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.

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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.

Carcinogenicity:
Exposures needed to cause the following health effect(s) are not expected during normal, intended use:
Contains a chemical or chemicals which can cause cancer.

Ingredient	C.A.S. No.	Class Description	Regulation
Titanium Dioxide	13463-67-7	Grp. 2B: Possible human carc.	International Agency for Research on Cancer

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
YTTERBIUM FLUORIDE (YbF3)	Ingestion	Rat	LD50 > 5,000 mg/kg
DIURETHANE DIMETHACRYLATE (UDMA)	Ingestion	Rat	LD50 > 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
1,12-DODECANE DIMETHYCRYLATE (DDDMA)	Ingestion	similar compounds	LD50 2000-5000 mg/kg
ETHYL 4-DIMETHYL AMINOBENZOATE (EDMAB)	Ingestion		LD50 estimated to be 300 - 2,000 mg/kg
Titanium Dioxide	Dermal	Rabbit	LD50 > 10,000 mg/kg
Titanium Dioxide	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 6.82 mg/l
Titanium Dioxide	Ingestion	Rat	LD50 > 10,000 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
SILANE TREATED CERAMIC	similar compounds	No significant irritation
SILANE TREATED SILICA		No significant irritation
Titanium Dioxide	Rabbit	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
SILANE TREATED CERAMIC	similar compounds	Mild irritant
SILANE TREATED SILICA		No significant irritation
Titanium Dioxide	Rabbit	No significant irritation

Skin Sensitization

Name	Species	Value
SILANE TREATED CERAMIC	similar compounds	Some positive data exist, but the data are not sufficient for classification
Pentanedioic acid, 2,2-dimethyl-4-methylene-, reaction products with glycidyl methacrylate	similar compounds	Some positive data exist, but the data are not sufficient for classification
Titanium Dioxide	Human and animal	Not sensitizing

Respiratory Sensitization

Name	Species	Value

Germ Cell Mutagenicity

Name	Route	Value
Titanium Dioxide	In Vitro	Not mutagenic
Titanium Dioxide	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
Titanium Dioxide	Ingestion	Multiple animal species	Not carcinogenic
Titanium Dioxide	Inhalation	Rat	Carcinogenic

Reproductive Toxicity

Reproductive and/or Developmental Effects

Name	Route	Value	Species	Test Result	Exposure Duration

Target Organ(s)

Specific Target Organ Toxicity - single exposure

Name	Route	Target Organ(s)	Value	Species	Test Result	Exposure Duration

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	
Titanium Dioxide	Inhalation	respiratory system	Some positive data exist, but the data are not sufficient for classification	Rat	LOAEL 0.010 mg/l	2 years
Titanium Dioxide	Inhalation	pulmonary fibrosis	All data are negative	Human	NOAEL Not available	occupational exposure

Aspiration Hazard

Name	Value

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 in a permitted waste incineration facility. Proper destruction may require the use of additional fuel during incineration processes. Empty drums/barrels/containers used for transporting and handling hazardous chemicals (chemical substances/mixtures/preparations classified as Hazardous as per applicable regulations) shall be considered, stored, treated & disposed of as hazardous wastes unless otherwise defined by applicable waste regulations. Consult with the respective regulating authorities to determine the available treatment and disposal facilities.

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

This material contains a chemical which requires export notification under TSCA Section 12[b]:

Ingredient (Category if applicable)	C.A.S. No	Regulation	Status
BENZOTRIAZOL	96478-09-0	Toxic Substances Control Act (TSCA) 5 SNUR or Consent Order Chemicals	Applicable

This material contains a chemical regulated by an EPA Significant New Use Rule (TSCA Section 5)

Ingredient (Category if applicable)	C.A.S. No	Reference
BENZOTRIAZOL	96478-09-0	40CFR721.8450

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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~Verified on 2014-08 by Henry Schein to be the most current version of the SDS. To be verified again on 2017-08. ~