



Safety Data Sheet

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SECTION 1: Identification

1.1. Product identifier

Filtek™ Bulk Fill Flowable Restorative

Product Identification Numbers

70-2014-0039-0, 70-2014-0040-8, 70-2014-0041-6, 70-2014-0042-4, 70-2014-0051-5, 70-2014-0052-3, 70-2014-0053-1, 70-2014-0054-9, 70-2014-0056-4, 70-2014-0060-6, 70-2014-0829-4, 70-2014-0830-2, 70-2014-0831-0, 70-2014-0832-8, 70-2014-0834-4, 70-2014-0835-1, 70-2014-0836-9, 70-2014-0837-7, 70-2014-0839-3, 70-2014-0840-1, 70-2014-0841-9, 70-2014-0842-7, 70-2014-0868-2, 70-2014-0869-0, 70-2014-0871-6, 70-2014-0938-3, 70-2014-0939-1, 70-2014-0940-9, 70-2014-0941-7, 70-2014-0944-1, 70-2014-0954-0, 70-2014-0955-7, 70-2014-0956-5, 70-2014-0957-3, 70-2014-1087-8, 70-2014-1088-6, 70-2014-1089-4, 70-2014-1090-2, 70-2014-1091-0, 70-2014-1092-8, 70-2014-1093-6, 70-2014-1094-4, 70-2014-1156-1, 70-2014-1300-5, 70-2014-1301-3, 70-2014-1302-1, 70-2014-1303-9, 70-2014-1304-7, 70-2014-1305-4, 70-2014-1306-2, 70-2014-1307-0, 70-2014-1308-8, 70-2014-1309-6, 70-2014-1437-5, 70-2014-1438-3, 70-2014-1439-1, 70-2014-1440-9, 70-2014-1441-7, 70-2014-1442-5, 70-2014-1443-3, 70-2014-1444-1, 70-2014-1455-7, 70-2014-1456-5, 70-2014-1457-3, 70-2014-1458-1, 70-2014-1459-9, 70-2014-1460-7, 70-2014-1461-5, 70-2014-1462-3, 70-2014-1472-2, 70-2014-1473-0
7100036588, 7100036668, 7100036669, 7100036670, 7100038838, 7100038839, 7100038860, 7100038861, 7100036671, 7100038863, 7100156373, 7100156376, 7100156377, 7100156374, 7100156418, 7100156417, 7100156427, 7100156416, 7100156428, 7100156419, 7100141225, 7100141226, 7100141207, 7100141223, 7100141210, 7100141221, 7100141184, 7100141185, 7100141186, 7100219137, 7100219138, 7100219139, 7100219140, 7100219142, 7100219384, 7100219360, 7100219485, 7100219361, 7100219141, 7100219377, 7100219362, 7100219373, 7100219374, 7100219383, 7100219535, 7100219522, 7100219500, 7100219501, 7100219499, 7100226069, 7100226070, 7100226071, 7100226072, 7100233420, 7100233421, 7100233422, 7100233391, 7100233392, 7100233413, 7100233423, 7100233424, 7100234886, 7100234900, 7100234887, 7100234901, 7100234902, 7100234903, 7100234888, 7100234904, 7100234889, 7100234926

1.2. Recommended use and restrictions on use

Recommended use

Dental Product, Bulk fill flowable 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.

Reproductive Toxicity: Category 1B.

2.2. Label elements

Signal word

Danger

Symbols

Exclamation mark | Health Hazard |

Pictograms



Hazard Statements

May cause an allergic skin reaction.

May damage fertility or the unborn child.

Precautionary Statements

Prevention:

Obtain special instructions before use.

Do not handle until all safety precautions have been read and understood.

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.

IF exposed or concerned: Get medical advice/attention.

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	50 - 60 Trade Secret *
Diurethane Dimethacrylate (UDMA)	72869-86-4	10 - 20 Trade Secret *
Substituted Dimethacrylate	27689-12-9	10 - 20 Trade Secret *

Ytterbium Fluoride (YbF ₃)	13760-80-0	1 - 10 Trade Secret *
Bisphenol A Diglycidyl Ether Dimethacrylate (BISGMA)	1565-94-2	1 - 5 Trade Secret *
Bisphenol A Polyethylene Glycol Diether Dimethacrylate (BISGMA-6)	41637-38-1	1 - 5 Trade Secret *
Triethylene Glycol Dimethacrylate (TEGDMA)	109-16-0	< 1 Trade Secret *
ETHYL 4-DIMETHYL AMINOBENZOATE (EDMAB)	10287-53-3	< 0.3 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

Allergic skin reaction (redness, swelling, blistering, and itching).

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

Exposure to extreme heat can give rise to thermal decomposition.

Hazardous Decomposition or By-Products

Substance

Carbon monoxide
Carbon dioxide

Condition

During Combustion
During Combustion

5.3. Special protective actions for fire-fighters

Wear full protective clothing, including helmet, self-contained, positive pressure or pressure demand breathing apparatus, bunker coat and pants, bands around arms, waist and legs, face mask, and protective covering for exposed areas of the head.

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

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 with an appropriate solvent selected by a qualified and authorized person. Ventilate the area with fresh air. Read and follow safety precautions on the solvent label and SDS. 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

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 handle until all safety precautions have been read and understood. Do not breathe 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. Use personal protective equipment (gloves, respirators, etc.) as required.

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
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 F):2.5 mg/m3;TWA(as dust):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 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****Appearance**

Physical state

Liquid

Color

Tooth

Specific Physical Form:

Viscous liquid-like paste

Odor

Slight Acrylate

Odor threshold

No Data Available

pH

Not Applicable

Melting point

No Data Available

Boiling Point

Not Applicable

Flash Point

Flash point > 93 °C (200 °F)

Evaporation rate

No Data Available

Flammability (solid, gas)

Not Applicable

Flammable Limits(LEL)

Not Applicable

Flammable Limits(UEL)

Not Applicable

Vapor Pressure

Not Applicable

Vapor Density

Not Applicable

Density

1.5 g/cm³

Specific Gravity

1.5 [Ref Std: WATER=1]

Solubility in Water

Negligible

Solubility- non-water

No Data Available

Partition coefficient: n-octanol/ water

No Data Available

Autoignition temperature

No Data Available

Decomposition temperature

No Data Available

Viscosity

No Data Available

Molecular weight

No Data Available

Volatile Organic Compounds

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

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:

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:

May be harmful if swallowed.

Gastrointestinal Irritation: Signs/symptoms may include abdominal pain, stomach upset, nausea, vomiting and diarrhea.

May cause additional health effects (see below).

Additional Health Effects:

Reproductive/Developmental Toxicity:

Contains a chemical or chemicals which can cause birth defects or other reproductive harm.

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
Substituted Dimethacrylate	Dermal	Professional judgment	LD50 estimated to be > 5,000 mg/kg
Substituted Dimethacrylate	Ingestion	Rat	LD50 > 17,600 mg/kg
Diurethane Dimethacrylate (UDMA)	Dermal	Professional judgment	LD50 estimated to be > 5,000 mg/kg
Diurethane Dimethacrylate (UDMA)	Ingestion	Rat	LD50 > 5,000 mg/kg
Ytterbium Fluoride (YbF ₃)	Dermal	Professional judgment	LD50 estimated to be > 5,000 mg/kg
Ytterbium Fluoride (YbF ₃)	Ingestion	Rat	LD50 > 5,000 mg/kg
Bisphenol A Diglycidyl Ether Dimethacrylate (BISGMA)	Dermal	Professional judgment	LD50 estimated to be > 5,000 mg/kg
Bisphenol A Diglycidyl Ether Dimethacrylate (BISGMA)	Ingestion	Rat	LD50 > 11,700 mg/kg
Bisphenol A Polyethylene Glycol Diether Dimethacrylate (BISGMA-6)	Dermal	Rat	LD50 > 2,000 mg/kg
Bisphenol A Polyethylene Glycol Diether Dimethacrylate (BISGMA-6)	Ingestion	Rat	LD50 > 35,000 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
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

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Silane Treated Ceramic	similar compounds	No significant irritation
Substituted Dimethacrylate	Rabbit	No significant irritation
Bisphenol A Diglycidyl Ether Dimethacrylate (BISGMA)	Rabbit	No significant irritation
Bisphenol A Polyethylene Glycol Diether Dimethacrylate (BISGMA-6)	Rabbit	Minimal irritation
ETHYL 4-DIMETHYL AMINO BENZOATE (EDMAB)	Rabbit	No significant irritation
Triethylene Glycol Dimethacrylate (TEGDMA)	Guinea pig	Mild irritant

Serious Eye Damage/Irritation

Name	Species	Value
Silane Treated Ceramic	similar compounds	Mild irritant
Substituted Dimethacrylate	Rabbit	Mild irritant
Ytterbium Fluoride (YbF ₃)	Professional judgment	Mild irritant

Bisphenol A Diglycidyl Ether Dimethacrylate (BISGMA)	In vitro data	No significant irritation
Bisphenol A Polyethylene Glycol Diether Dimethacrylate (BISGMA-6)	Rabbit	No significant irritation
ETHYL 4-DIMETHYL AMINOBENZOATE (EDMAB)	Rabbit	No significant irritation
Triethylene Glycol Dimethacrylate (TEGDMA)	Professional judgement	Moderate irritant

Skin Sensitization

Name	Species	Value
Silane Treated Ceramic	similar compounds	Not classified
Substituted Dimethacrylate	Guinea pig	Not classified
Diurethane Dimethacrylate (UDMA)	Guinea pig	Sensitizing
Bisphenol A Diglycidyl Ether Dimethacrylate (BISGMA)	Mouse	Not classified
Bisphenol A Polyethylene Glycol Diether Dimethacrylate (BISGMA-6)	Guinea pig	Not classified
ETHYL 4-DIMETHYL AMINOBENZOATE (EDMAB)		Not classified
Triethylene Glycol Dimethacrylate (TEGDMA)	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
Substituted Dimethacrylate	In Vitro	Not mutagenic
Bisphenol A Diglycidyl Ether Dimethacrylate (BISGMA)	In Vitro	Not mutagenic
Bisphenol A Polyethylene Glycol Diether Dimethacrylate (BISGMA-6)	In Vitro	Not mutagenic
ETHYL 4-DIMETHYL AMINOBENZOATE (EDMAB)	In vivo	Not mutagenic
ETHYL 4-DIMETHYL AMINOBENZOATE (EDMAB)	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

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
Bisphenol A Diglycidyl Ether Dimethacrylate (BISGMA)	Ingestion	Not classified for development	Rat	NOAEL 1,000 mg/kg/day	during gestation
ETHYL 4-DIMETHYL AMINOBENZOATE (EDMAB)	Ingestion	Not classified for female reproduction	Rat	NOAEL 600 mg/kg/day	premating into lactation
ETHYL 4-DIMETHYL AMINOBENZOATE (EDMAB)	Ingestion	Not classified for development	Rat	NOAEL 50 mg/kg/day	premating into lactation
ETHYL 4-DIMETHYL AMINOBENZOATE (EDMAB)	Ingestion	Toxic to male reproduction	Rat	NOAEL 50 mg/kg/day	53 days
Triethylene Glycol Dimethacrylate (TEGDMA)	Ingestion	Not classified for female reproduction	Mouse	NOAEL 1 mg/kg/day	1 generation

Triethylene Glycol Dimethacrylate (TEGDMA)	Ingestion	Not classified for male reproduction	Mouse	NOAEL 1 mg/kg/day	1 generation
Triethylene Glycol Dimethacrylate (TEGDMA)	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 hematopoietic system liver heart skin gastrointestinal tract bone, teeth, nails, and/or hair immune system muscles nervous system eyes kidney and/or bladder respiratory system vascular system	Not classified	Rat	NOAEL 1,000 mg/kg/day	90 days
ETHYL 4-DIMETHYL AMINO BENZOATE (EDMAB)	Ingestion	hematopoietic system	Some positive data exist, but the data are not sufficient for classification	Rat	NOAEL 74 mg/kg/day	28 days
ETHYL 4-DIMETHYL AMINO BENZOATE (EDMAB)	Ingestion	liver heart endocrine system gastrointestinal tract bone, teeth, nails, and/or hair immune system muscles nervous system eyes kidney and/or bladder respiratory system vascular system	Not classified	Rat	NOAEL 900 mg/kg/day	28 days
Triethylene Glycol Dimethacrylate (TEGDMA)	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

Reproductive toxicity

Respiratory or Skin Sensitization

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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