

Safety Data Sheet

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SECTION 1: Identification

1.1. Product identifier

3MTM FiltekTM Universal Restorative - All Shades Except Pink Opaquer

Product Identification Numbers

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70-2014-0689-2, 70-2014-0690-0, 70-2014-0691-8, 70-2014-0692-6, 70-2014-0693-4, 70-2014-0694-2, 70-2014-0695-9, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-0691-8, 70-2014-06
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7100265962, 7100266019, 7100266020, 7100266017, 7100266018, 7100266010, 7100266016, 7100266015, 7100266021,
7100266004, 7100266006, 7100265910, 7100266005, 7100265909, 7100265908, 7100266013, 7100265999, 7100266007,
7100265911, 7100265912, 7100274203, 7100274204
```

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1.2. Recommended use and restrictions on use

Recommended use

Dental Product, Dental Restorative

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.

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.

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	40 - 70 Trade Secret *
Aromatic Urethane Dimethacrylate	1431303-59-1	10 - 30 Trade Secret *
Diurethane Dimethacrylate (UDMA)	72869-86-4	1 - 10 Trade Secret *
Ytterbium Fluoride (Ybf3)	13760-80-0	1 - 10 Trade Secret *
1,12-Dodecane Dimethycrylate (DDDMA)	72829-09-5	1 - 5 Trade Secret *
Silane Treated Silica	248596-91-0	1 - 5 Trade Secret *
Silane Treated Zirconia	None	1 - 5 Trade Secret *
Water	7732-18-5	1 - 5 Trade Secret *
N,N-DIMETHYLBENZOCAINE	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:

If exposed, flush eyes with large amounts of water. Remove contact lenses if easy to do. Continue rinsing. If signs/symptoms develop, 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

None inherent in this product.

Hazardous Decomposition or By-Products Substance

<u>Substance</u> <u>Condition</u>

Carbon monoxide Carbon dioxide 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

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. 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. A no-touch technique is recommended. If skin contact occurs, wash skin with soap and water. If product contacts glove, remove and discard glove, wash hands immediately with soap and water and then re-glove.

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.

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 stateSolidColorTooth

Specific Physical Form: Paste

Slight Acrylate Odor **Odor threshold** No Data Available рH Not Applicable **Melting point** No Data Available **Boiling Point** Not Applicable Flash Point No flash point **Evaporation rate** Not Applicable Not Classified Flammability (solid, gas) 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 Solubility in Water Negligible

Solubility in Water

Solubility- non-water

No Data Available

Partition coefficient: n-octanol/ water

Autoignition temperature

Decomposition temperature

Viscosity

No Data Available

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.

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.

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.

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	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
Aromatic Urethane Dimethacrylate	Dermal	Professio nal judgeme nt	LD50 estimated to be 2,000 - 5,000 mg/kg
Aromatic Urethane Dimethacrylate	Ingestion	Rat	LD50 > 2,000 mg/kg
Ytterbium Fluoride (Ybf3)	Dermal	Professio nal judgeme nt	LD50 estimated to be > 5,000 mg/kg
Ytterbium Fluoride (Ybf3)	Ingestion	Rat	LD50 > 5,000 mg/kg
Diurethane Dimethacrylate (UDMA)	Dermal	Professio nal judgeme nt	LD50 estimated to be > 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)	Dermal	Professio nal judgeme nt	LD50 estimated to be 2,000 - 5,000 mg/kg
1,12-Dodecane Dimethycrylate (DDDMA)	Ingestion	similar compoun ds	LD50 2000-5000 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
N,N-DIMETHYLBENZOCAINE	Dermal	Rat	LD50 > 2,000 mg/kg
N,N-DIMETHYLBENZOCAINE	Ingestion	Rat	LD50 > 2,000 mg/kg

 \overline{ATE} = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Silane Treated Ceramic	similar compoun ds	No significant irritation
Aromatic Urethane Dimethacrylate	In vitro data	No significant irritation
Silane Treated Silica	Professio nal judgeme nt	No significant irritation
Silane Treated Zirconia	Rabbit	No significant irritation
N,N-DIMETHYLBENZOCAINE	Rabbit	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
Silane Treated Ceramic	similar compoun ds	Mild irritant
Aromatic Urethane Dimethacrylate	In vitro data	No significant irritation
Ytterbium Fluoride (Ybf3)	Professio nal judgeme nt	Mild irritant
Silane Treated Silica	Professio nal judgeme nt	No significant irritation
Silane Treated Zirconia	Rabbit	Mild irritant
N,N-DIMETHYLBENZOCAINE	Rabbit	No significant irritation

Skin Sensitization

Name	Species	Value
Silane Treated Ceramic	similar compoun ds	Not classified
Aromatic Urethane Dimethacrylate	Professio nal judgeme nt	Sensitizing
Diurethane Dimethacrylate (UDMA)	Guinea pig	Sensitizing
N,N-DIMETHYLBENZOCAINE		Not classified

Respiratory Sensitization

For the component/components, either no data are currently available or the data are not sufficient for classification.

Germ Cell Mutagenicity

Germ Cen Mutagementy		
Name	Route	Value
Aromatic Urethane Dimethacrylate	In Vitro	Not mutagenic
Silane Treated Zirconia	In Vitro	Some positive data exist, but the data are not sufficient for classification
N,N-DIMETHYLBENZOCAINE	In vivo	Not mutagenic
N,N-DIMETHYLBENZOCAINE	In Vitro	Some positive data exist, but the data are not sufficient for classification

Carcinogenicity

Caremogenicity			
Name	Route	Species	Value
Silane Treated Ceramic	Inhalation	similar compoun ds	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

Reproductive Toxicity

Reproductive and/or Developmental Effects

Reproductive and/or Developmental Effects							
Name	Route	Value	Species	Test Result	Exposure Duration		
N,N-DIMETHYLBENZOCAINE	Ingestion	Not classified for female reproduction	Rat	NOAEL 600 mg/kg/day	premating into lactation		
N,N-DIMETHYLBENZOCAINE	Ingestion	Not classified for development	Rat	NOAEL 50 mg/kg/day	premating into lactation		
N,N-DIMETHYLBENZOCAINE	Ingestion	Toxic to male reproduction	Rat	NOAEL 50	53 days		

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3M [™] Filtek [™] Universal Restorative - All Shades Except Pink Opaquer	03/31/23	

· ·		ma/ka/dav	
· ·		mg/kg/dav	

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 compoun ds	NOAEL Not available	
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
N,N- DIMETHYLBENZOCAIN E	Ingestion	hematopoietic system	Some positive data exist, but the data are not sufficient for classification	Rat	NOAEL 74 mg/kg/day	28 days
N,N- DIMETHYLBENZOCAIN E	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

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

Additional TSCA Information

Components	CAS No	Additional Information
Silane Treated Silica	248596-91-0	Allowed use(s): Coating additive.

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:
 39-3531-9
 Version Number:
 2.10

 Issue Date:
 03/31/23
 Supercedes Date:
 11/03/22

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