



Safety Data Sheet

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This Safety Data Sheet has been prepared in accordance with the Canadian Hazardous Products Regulations.

SECTION 1: Identification

1.1. Product identifier

3M™ Filtek™ One Bulk Fill Restorative

1.2. Recommended use and restrictions on use

Intended Use

Dental Restorative

Specific Use

Restrictions on Use: For use only by dental professionals in approved indications

Restrictions on use

Not applicable

1.3. Supplier's details

Company:	3M Canada Company
Division:	Oral Care Solutions Division
Address:	1840 Oxford Street East, Post Office Box 5757, London, Ontario N6A 4T1
Telephone:	(800) 364-3577
Website:	www.3M.ca

1.4. Emergency telephone number

Medical Emergency Telephone: 1-800-3M HELPS / 1-800-364-3577; Transportation Emergency Telephone (CANUTEC): (613) 996-6666

SECTION 2: Hazard identification

This product is exempt from hazard classification according to Canadian Hazardous Products Regulations for the following reason(s):

Cosmetic, device, drug or food as defined in section 2 of the Food and Drugs Act;

2.1. Classification of the substance or mixture

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/fume/gas/mist/vapours/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. Take off contaminated clothing and wash it before reuse. IF exposed or concerned: Get medical advice/attention.

Storage:

Store locked up.

Disposal:

Dispose of contents/container in accordance with applicable local/regional/national/international regulations.

2.3. Other hazards

None known.

SECTION 3: Composition/information on ingredients

This material is a mixture.

Ingredient	C.A.S. No.	% by Wt	Common Name
Silane Treated Ceramic	444758-98-9	60 - 70 Trade Secret *	No Data Available
Aromatic Urethane Dimethacrylate	1431303-59-1	10 - 20 Trade Secret *	No Data Available
Diurethane Dimethacrylate (UDMA)	72869-86-4	1 - 10 Trade Secret *	2-Propenoic acid, 2-methyl-, 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl ester
Silane Treated Silica	248596-91-0	1 - 10 Trade Secret *	No Data Available
Ytterbium Fluoride (YbF3)	13760-80-0	1 - 10 Trade Secret *	No Data Available
Silane Treated Zirconia	None	< 5 Trade Secret *	Not Applicable
Water	7732-18-5	< 5 Trade Secret *	Water
1,12-Dodecane Dimethacrylate (DDDMA)	72829-09-5	< 2.5 Trade Secret *	No Data Available
ETHYL 4-DIMETHYL	10287-53-3	< 0.3 Trade Secret *	Benzoic acid, 4-(dimethylamino)-, ethyl

AMINO BENZOATE (EDMAB)			ester
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*The actual concentration of this ingredient 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

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

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 vapours, 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. 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/vapours/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

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.

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

Physical state	Solid
Specific Physical Form:	Paste
Colour	White
Odour	Slight Acrylate
Odour threshold	<i>No Data Available</i>
pH	<i>Not Applicable</i>

Melting point/Freezing point	<i>No Data Available</i>
Boiling point	<i>Not Applicable</i>
Flash Point	No flash point
Evaporation rate	<i>No Data Available</i>
Flammability (solid, gas)	Not Classified
Flammable Limits(LEL)	<i>Not Applicable</i>
Flammable Limits(UEL)	<i>Not Applicable</i>
Vapour Pressure	<i>Not Applicable</i>
Vapour Density and/or Relative Vapour Density	<i>Not Applicable</i>
Density	1.9 g/cm ³
Relative density	1.9 [Ref Std: WATER=1]
Water solubility	Negligible
Solubility- non-water	<i>No Data Available</i>
Partition coefficient: n-octanol/ water	<i>No Data Available</i>
Autoignition temperature	<i>No Data Available</i>
Decomposition temperature	<i>No Data Available</i>
Viscosity/Kinematic Viscosity	<i>No Data Available</i>
Volatile Organic Compounds	<i>No Data Available</i>
Percent volatile	<i>No Data Available</i>
VOC Less H₂O & Exempt Solvents	<i>No Data Available</i>
Molecular weight	<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

Heat

10.5. Incompatible materials

Strong oxidizing agents

10.6. Hazardous decomposition products

Substance

None known.

Condition

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:

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	Professional judgement	LD50 Not applicable
Overall product	Ingestion	Rat	LD50 > 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
Aromatic Urethane Dimethacrylate	Dermal	Professional judgement	LD50 estimated to be 2,000 - 5,000 mg/kg
Aromatic Urethane Dimethacrylate	Ingestion	Rat	LD50 > 2,000 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
Diurethane Dimethacrylate (UDMA)	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Diurethane Dimethacrylate (UDMA)	Ingestion	Rat	LD50 > 5,000 mg/kg
Ytterbium Fluoride (YbF3)	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg

3M™ Filtek™ One Bulk Fill Restorative

Ytterbium Fluoride (YbF3)	Ingestion	Rat	LD50 > 5,000 mg/kg
1,12-Dodecane Dimethacrylate (DDDMA)	Dermal	Professional judgement	LD50 estimated to be 2,000 - 5,000 mg/kg
1,12-Dodecane Dimethacrylate (DDDMA)	Ingestion	similar compounds	LD50 2000-5000 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
ETHYL 4-DIMETHYL AMINOBENZOATE (EDMAB)	Dermal	Rat	LD50 > 2,000 mg/kg
ETHYL 4-DIMETHYL AMINOBENZOATE (EDMAB)	Ingestion	Rat	LD50 > 2,000 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Silane Treated Ceramic	similar compounds	No significant irritation
Aromatic Urethane Dimethacrylate	In vitro data	No significant irritation
Silane Treated Zirconia	Rabbit	No significant irritation
Silane Treated Silica	Professional judgement	No significant irritation
ETHYL 4-DIMETHYL AMINOBENZOATE (EDMAB)	Rabbit	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
Silane Treated Ceramic	similar compounds	Mild irritant
Aromatic Urethane Dimethacrylate	In vitro data	No significant irritation
Silane Treated Zirconia	Rabbit	Mild irritant
Ytterbium Fluoride (YbF3)	Professional judgement	Mild irritant
Silane Treated Silica	Professional judgement	No significant irritation
ETHYL 4-DIMETHYL AMINOBENZOATE (EDMAB)	Rabbit	No significant irritation

Skin Sensitization

Name	Species	Value
Silane Treated Ceramic	similar compounds	Not classified
Aromatic Urethane Dimethacrylate	Professional judgement	Sensitizing
Diurethane Dimethacrylate (UDMA)	Guinea pig	Sensitizing
ETHYL 4-DIMETHYL AMINOBENZOATE (EDMAB)		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

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
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

Carcinogenicity

Name	Route	Species	Value
Silane Treated Ceramic	Inhalation	similar compounds	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**

Name	Route	Value	Species	Test result	Exposure Duration
ETHYL 4-DIMETHYL AMINOBENZOATE (EDMAB)	Ingestion	Not classified for female reproduction	Rat	NOAEL 600 mg/kg/day	prematuring into lactation
ETHYL 4-DIMETHYL AMINOBENZOATE (EDMAB)	Ingestion	Not classified for development	Rat	NOAEL 50 mg/kg/day	prematuring into lactation
ETHYL 4-DIMETHYL AMINOBENZOATE (EDMAB)	Ingestion	Toxic to male reproduction	Rat	NOAEL 50 mg/kg/day	53 days

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	
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
ETHYL 4-DIMETHYL AMINOBENZOATE (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 AMINOBENZOATE (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

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

No data available.

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.

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. Safety, health and environmental regulations/legislation specific for the substance or mixture****Global inventory status**

Contact 3M for more information.

SECTION 16: Other information

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.

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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