



## Safety Information Sheet for Medical Devices

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**Document group:** 36-6354-9 **Version number:** 1.00  
**Revision date:** 05/12/2019 **Supersedes date:** Initial issue.  
**Transportation version number:** 1.00 (05/12/2019)

A safety data sheet is not required for this Product. This Safety Information Sheet has been created on a voluntary basis.

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

3M™ FILTEK™ ONE BULK FILL RESTORATIVE

##### Product Identification Numbers

70-2014-0467-3	70-2014-0468-1	70-2014-0469-9	70-2014-0470-7	70-2014-0471-5
70-2014-0472-3	70-2014-0473-1	70-2014-0474-9	70-2014-0475-6	70-2014-0476-4
70-2014-0477-2	70-2014-0478-0	70-2014-0481-4	70-2014-0482-2	70-2014-0483-0
70-2014-0484-8	70-2014-0485-5	70-2014-0486-3	70-2014-0487-1	70-2014-0488-9
70-2014-0489-7	70-2014-0490-5	70-2014-0491-3	70-2014-0492-1	70-2014-0493-9
70-2014-0494-7	70-2014-0495-4	70-2014-0496-2	70-2014-0497-0	70-2014-0498-8
70-2014-0499-6	70-2014-0500-1	70-2014-0501-9	70-2014-0502-7	70-2014-0506-8
70-2014-0508-4	70-2014-0639-7	70-2014-1143-9	70-2014-1144-7	70-2014-1145-4
70-2014-1146-2	70-2014-1147-0	70-2014-1148-8	70-2014-1149-6	70-2014-1150-4
70-2014-1151-2	70-2014-1152-0	70-2014-1153-8	70-2014-1154-6	
7100109998	7100109985	7100109997	7100109992	7100110000
7100109994	7100109993	7100109986	7100109991	7100110007
7100109989	7100109999	7010343366	7010389463	7010304361
7010389464	7010343367	7010389465	7010317631	7010389466
7010343368	7010296868	7010317633	7010389472	7010389467
7010343369	7010389468	7010317632	7010389469	7010343370
7010304362	7010389470	7010343371	7010389471	7010343373
7010317634	7100135777	7100141095	7100141100	7100141479
7100141087	7100141085	7100141084	7100141121	7100141092
7100141091	7100141127	7100141124	7100141093	

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

##### Identified uses

Medical device; refer to Instructions for Use

### 1.3 Details of the supplier of the safety information sheet for medical devices

**Address:** 3M United Kingdom PLC, 3M Centre, Cain Road, Bracknell, Berkshire, RG12 8HT.  
**Telephone:** +44 (0)1344 858 000  
**E Mail:** tox.uk@mmm.com  
**Website:** www.3M.com/uk

### 1.4. Emergency telephone number

+44 (0)1344 858 000

## SECTION 2: Hazard identification

### 2.1. Classification of the substance or mixture

#### CLP REGULATION (EC) No 1272/2008

This product is a medical device as defined in Directive 93/42/EEC (MDD), which is invasive or used in direct physical contact with the human body, and therefore is exempt from the requirements of classification and labelling according to Regulation (EC) No. 1272/2008 (CLP; Article 1, paragraph 5). Although not required, the classification and label information, as applicable, is provided below.

#### CLASSIFICATION:

Skin Sensitization, Category 1B - Skin Sens. 1B; H317

Hazardous to the Aquatic Environment (Chronic), Category 3 - Aquatic Chronic 3; H412

For full text of H phrases, see Section 16.

### 2.2. Label elements

#### CLP REGULATION (EC) No 1272/2008

#### SIGNAL WORD

WARNING.

#### Symbols:

GHS07 (Exclamation mark) |

#### Pictograms



#### Ingredients:

Ingredient	CAS Nbr	EC No.	% by Wt
Urethane dimethacrylate (UDMA)	72869-86-4	276-957-5	1 - 10
Aliphatic dimethacrylate	72829-09-5	276-900-4	< 10

#### HAZARD STATEMENTS:

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

#### PRECAUTIONARY STATEMENTS

**Prevention:**

P280E Wear protective gloves.

**Response:**

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

**Disposal:**

P501 Dispose of contents/container in accordance with applicable local/regional/national/international regulations.

**2.3. Other hazards**

For information on hazards and safe use, please consider the corresponding sections of this document.

**SECTION 3: Composition/information on ingredients**

<b>Ingredient</b>	<b>CAS Nbr</b>	<b>EC No.</b>	<b>% by Wt</b>	<b>Classification</b>
Silane treated ceramic	444758-98-9		60 - 70	Substance not classified as hazardous
Aromatic urethane dimethacrylate	1431303-59-1		10 - 20	Substance not classified as hazardous
Urethane dimethacrylate (UDMA)	72869-86-4	276-957-5	1 - 10	Aquatic Chronic 3, H412 Skin Sens. 1B, H317
Ytterbium fluorid	13760-80-0	237-354-2	1 - 10	Substance not classified as hazardous
Aliphatic dimethacrylate	72829-09-5	276-900-4	< 10	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335; Aquatic Acute 1, H400,M=10; Aquatic Chronic 1, H410,M=1
Silane treated silica	248596-91-0		1 - 10	Substance not classified as hazardous
Silane treated zirconia ceramic	None		< 5	Substance not classified as hazardous
Water	7732-18-5	231-791-2	< 5	Substance not classified as hazardous

Please see section 16 for the full text of any H statements referred to in this section

For information on ingredient occupational exposure limits or PBT or vPvB status, see sections 8 and 12 of this SIS

**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.

## SECTION 5: Fire-fighting measures

### 5.1. 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. Advice 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 SIS 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

Refer to Instructions for Use (IFU) for more information.

## 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 SIS.

#### Biological limit values

No biological limit values exist for any of the components listed in Section 3 of this safety information sheet.

## 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.

#### Applicable Norms/Standards

Use eye protection conforming to EN 166

#### 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

Solid.

Colour

Multicolor

Specific Physical Form:

Paste

Odor

Slight Acrylate

pH

*Not applicable.*

Boiling point/boiling range

*Not applicable.*

Melting point

*No data available.*

Flammability (solid, gas)

Not classified

Explosive properties

Not classified

Oxidising properties

Not classified

Flash point

No flash point

Autoignition temperature

*No data available.*

Flammable Limits(LEL)

*Not applicable.*

Flammable Limits(UEL)

*Not applicable.*

Relative density

1.9 [Ref Std:WATER=1]

Water solubility

Negligible

Viscosity

*No data available.*

Density

1.9 g/cm<sup>3</sup>

### 9.2. Other information

EU 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 polymerisation will not occur.

#### 10.4 Conditions to avoid

Heat.

#### 10.5 Incompatible materials

Strong oxidising 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 agree with the EU material classification in Section 2 and/or the ingredient classifications in Section 3 if specific ingredient classifications are mandated by a competent authority. In addition, statements and data presented in Section 11 are based on UN GHS calculation rules and classifications derived from 3M assessments.

### 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 odour; 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

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

#### 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

**3M™ FILTEK™ ONE BULK FILL RESTORATIVE**  
05/12/2019

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
Silane treated zirconia ceramic	Dermal		LD50 estimated to be > 5,000 mg/kg
Silane treated zirconia ceramic	Ingestion		LD50 estimated to be 2,000 - 5,000 mg/kg
Urethane dimethacrylate (UDMA)	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Urethane dimethacrylate (UDMA)	Ingestion	Rat	LD50 > 5,000 mg/kg
Ytterbium fluorid	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Ytterbium fluorid	Ingestion	Rat	LD50 > 5,000 mg/kg
Aliphatic dimethacrylate	Dermal	Professional judgement	LD50 estimated to be 2,000 - 5,000 mg/kg
Aliphatic dimethacrylate	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

ATE = acute toxicity estimate

### Skin Corrosion/Irritation

Name	Species	Value
Silane treated ceramic	similar compounds	No significant irritation
Silane treated zirconia ceramic	Rabbit	No significant irritation
Silane treated silica	Professional judgement	No significant irritation

### Serious Eye Damage/Irritation

Name	Species	Value
Silane treated ceramic	similar compounds	Mild irritant
Silane treated zirconia ceramic	Rabbit	Mild irritant
Ytterbium fluorid	Professional judgement	Mild irritant
Silane treated silica	Professional judgement	No significant irritation

### Skin Sensitisation

Name	Species	Value
Silane treated ceramic	similar compounds	Not classified
Urethane dimethacrylate (UDMA)	Guinea pig	Sensitising

### Respiratory Sensitisation

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

### Germ Cell Mutagenicity

Name	Route	Value
Silane treated zirconia ceramic	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 ceramic	Inhalation	Multiple animal species	Some positive data exist, but the data are not sufficient for classification

### Reproductive Toxicity

### Reproductive and/or Developmental Effects

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

**Target Organ(s)**

**Specific Target Organ Toxicity - single exposure**

For the component/components, either no data is currently available or the data is 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 ceramic	Inhalation	pulmonary fibrosis	Not classified	Multiple animal species	NOAEL Not available	
Silane treated zirconia ceramic	Inhalation	respiratory system	Not classified	Human	NOAEL Not available	occupational exposure

**Aspiration Hazard**

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

**Please contact the address or phone number listed on the first page of the SIS for additional toxicological information on this material and/or its components.**

The product was evaluated by a toxicologist to be safe for its intended use.

**SECTION 12: Ecological information**

**The information below may not agree with the EU material classification in Section 2 and/or the ingredient classifications in Section 3 if specific ingredient classifications are mandated by a competent authority. In addition, statements and data presented in Section 12 are based on UN GHS calculation rules and classifications derived from 3M assessments.**

**12.1. Toxicity**

No product test data available.

Material	CAS #	Organism	Type	Exposure	Test endpoint	Test result
Silane treated ceramic	444758-98-9		Data not available or insufficient for classification			
Aromatic urethane dimethacrylate	1431303-59-1		Data not available or insufficient for classification			
Urethane dimethacrylate (UDMA)	72869-86-4	Zebra Fish	Experimental	96 hours	LC50	10.1 mg/l
Urethane dimethacrylate (UDMA)	72869-86-4	Water flea	Experimental	48 hours	EC50	>100 mg/l
Urethane dimethacrylate (UDMA)	72869-86-4	Green algae	Endpoint not reached	72 hours	Effect Growth Rate Conc 50%	>100 mg/l
Urethane dimethacrylate (UDMA)	72869-86-4	Green algae	Endpoint not reached	72 hours	Effect Conc. 10% - Growth Rate	>100 mg/l
Ytterbium fluorid	13760-80-0	Water flea	Experimental	48 hours	No tox obs at lmt of water sol	>100 mg/l
Aliphatic dimethacrylate	72829-09-5	Green Algae	Experimental	72 hours	EC50	17 µg/l
Aliphatic dimethacrylate	72829-09-5	Water flea	Experimental	48 hours	EC50	>100 mg/l
Aliphatic dimethacrylate	72829-09-5	Green Algae	Experimental	72 hours	Effect Concentration 10%	6.4 µg/l
Silane treated silica	248596-91-0		Data not available or insufficient for			



**3M™ FILTEK™ ONE BULK FILL RESTORATIVE**  
05/12/2019

			classification			
Silane treated zirconia ceramic	None		Data not available or insufficient for classification			

**12.2. Persistence and degradability**

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Silane treated ceramic	444758-98-9	Data not available or insufficient			N/A	
Aromatic urethane dimethacrylate	1431303-59-1	Data not available or insufficient			N/A	
Urethane dimethacrylate (UDMA)	72869-86-4	Experimental Biodegradation	28 days	CO2 evolution	22 %CO2 evolution/THCO2 evolution (does not pass 10-day window)	OECD 301B - Modified sturm or CO2
Ytterbium fluorid	13760-80-0	Data not available or insufficient			N/A	
Aliphatic dimethacrylate	72829-09-5	Experimental Biodegradation	28 days	CO2 evolution	97.3 %CO2 evolution/THCO2 evolution	OECD 301B - Modified sturm or CO2
Silane treated silica	248596-91-0	Data not available or insufficient			N/A	
Silane treated zirconia ceramic	None	Data not available or insufficient			N/A	

**12.3 : Bioaccumulative potential**

Material	Cas No.	Test type	Duration	Study Type	Test result	Protocol
Silane treated ceramic	444758-98-9	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Aromatic urethane dimethacrylate	1431303-59-1	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Urethane dimethacrylate (UDMA)	72869-86-4	Experimental Bioconcentration		Log Kow	3.39	Other methods
Ytterbium fluorid	13760-80-0	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Aliphatic dimethacrylate	72829-09-5	Estimated Bioconcentration		Bioaccumulation factor	6.6	Estimated: Bioconcentration factor
Silane treated silica	248596-91-0	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Silane treated zirconia ceramic	None	Data not available or insufficient for classification	N/A	N/A	N/A	N/A

**12.4. Mobility in soil**

Please contact manufacturer for more details

**12.5. Results of the PBT and vPvB assessment**

This material does not contain any substances that are assessed to be a PBT or vPvB

**12.6. Other adverse effects**

No information available.

**SECTION 13: Disposal considerations**

**13.1 Waste treatment methods**

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

Refer to Instructions for Use (IFU) for more information.

**EU waste code (product as sold)**

180106\*      Chemicals consisting of or containing dangerous substances.

**SECTION 14: Transportation information**

70-2014-0467-3,    70-2014-0468-1,    70-2014-0469-9,    70-2014-0470-7,  
70-2014-0471-5,    70-2014-0472-3,    70-2014-0473-1,    70-2014-0474-9,  
70-2014-0475-6,    70-2014-0476-4,    70-2014-0477-2,    70-2014-0478-0,  
70-2014-0501-9,    70-2014-0639-7

Not hazardous for transportation

70-2014-0489-7

70-2014-0490-5

70-2014-0491-3

70-2014-0492-1

70-2014-0493-9

70-2014-0494-7

70-2014-0495-4

70-2014-0496-2

70-2014-0497-0

70-2014-0498-8

70-2014-0481-4

70-2014-0499-6

70-2014-0500-1

70-2014-0502-7

70-2014-0506-8

70-2014-0508-4

70-2014-1143-9

70-2014-1144-7

70-2014-1145-4

70-2014-1146-2  
70-2014-1147-0  
70-2014-0482-2  
70-2014-1148-8  
70-2014-1149-6  
70-2014-1150-4  
70-2014-1151-2  
70-2014-1152-0  
70-2014-1153-8  
70-2014-1154-6  
70-2014-0483-0  
70-2014-0484-8  
70-2014-0485-5  
70-2014-0486-3  
70-2014-0487-1  
70-2014-0488-9

ADR/IMDG/IATA: Not restricted for transport.

## **SECTION 15: Regulatory information**

### **15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

#### **Global inventory status**

Contact the manufacturer for more information

## **SECTION 16: Other information**

### **List of relevant H statements**

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

#### **Revision information:**

Revision information not available

The product to which this Safety Information Sheet applies is classified as a medical device according to the EU Medical Device Regulation EU 2017/745. \_x000D\_  
Medical devices which are invasive or used in direct physical contact with the human body are exempt from the requirements of classification and labelling according to Regulation (EC) No. 1272/2008 (CLP; Article 1, paragraph 5). \_x000D\_  
The EU Medical Device Regulation does not foresee the use of Safety Data sheets for medical devices which are invasive or used in direct physical contact with the human body, as the safe use of the product is described through the Instructions for Use and /or the labelling for the product. Nevertheless, the 3M Safety Information Sheet is provided as a further service to customers to provide additional toxicology and chemical information on the product. In case of further questions, please contact your 3M representative listed on the Safety Information Sheet.

**3M United Kingdom Safety Information Sheets are available at [www.3M.com/uk](http://www.3M.com/uk)**