Safety Information Sheet for Medical Devices

Document group:	40-4961-5	**Version number:**	1.00
Revision date:	20/07/2020	**Supersedes date:**	Initial issue.

Transportation version number: 1.00 (20/07/2020)

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

IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier
3M™ Filtek™ Universal Restorative - All Shades

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 data sheet

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

This product is a kit or a multipart product which consists of multiple, independently packaged components. Safety Information Sheet for Medical Devices for each of these components is included. Please do not separate the component Safety Information Sheet for Medical Devices from this cover page. The document numbers of the Safety Information Sheet for Medical Devices for components of this product are:

39-3531-9, 40-4251-1

TRANSPORTATION INFORMATION

KIT LABEL

2.1. Classification of the substance or mixture
Please refer to Kit Components

Revision information:
Revision information not available

Safety Information Sheet for Medical Devices

Document group:	39-3531-9	**Version number:**	1.00
Revision date:	25/10/2019	**Supersedes date:**	Initial issue.

Transportation version number: 1.00 (25/10/2019)

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™ Universal Restorative - All shades except Pink Opaquer

Product Identification Numbers

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	70-2014-0696-7	70-2014-0697-5	70-2014-0699-1
70-2014-0700-7	70-2014-0701-5	70-2014-0702-3	70-2014-0703-1	70-2014-0704-9
70-2014-0705-6	70-2014-0706-4	70-2014-0707-2	70-2014-0709-8	70-2014-0710-6
70-2014-0711-4	70-2014-0712-2	70-2014-0713-0	70-2014-0714-8	70-2014-0715-5
70-2014-0716-3	70-2014-0717-1	70-2014-0719-7	70-2014-0720-5	70-2014-0721-3
70-2014-0722-1	70-2014-0723-9	70-2014-0724-7	70-2014-0725-4	70-2014-0726-2
70-2014-0727-0	70-2014-0729-6	70-2014-0730-4	70-2014-0731-2	70-2014-0732-0
70-2014-0733-8	70-2014-0734-6	70-2014-0735-3	70-2014-0736-1	70-2014-0737-9
70-2014-0739-5	70-2014-0740-3	70-2014-0741-1	70-2014-0742-9	70-2014-0743-7
70-2014-0744-5	70-2014-0745-2	70-2014-0746-0	70-2014-0747-8	70-2014-0749-4
70-2014-0750-2	70-2014-0751-0	70-2014-0752-8	70-2014-0753-6	70-2014-0754-4
70-2014-0765-0	70-2014-0766-8	70-2014-0767-6	70-2014-0768-4	70-2014-0769-2
70-2014-0770-0				

7100186753	7100186712	7100186763	7100186764	7100186745
7100186772	7100186783	7100186784	7100186746	7100186768
7100186749	7100186747	7100186770	7100186785	7100186786
7100186780	7100186756	7100186771	7100186752	7100186751
7100186773	7100186762	7100186761	7100186750	7100186757
7100186760	7100186759	7100186758	7100187416	7100187401
7100187398	7100186776	7100186748	7100186779	7100186778
7100186765	7100186766	7100186767	7100186775	7100186774
7100187150	7100187149	7100187406	7100187407	7100187408
7100187409	7100187148	7100187147	7100187393	7100187400

7100187399	7100187395	7100187403	7100187146	7100187151
7100187152	7100187370	7100187404	7100187405	7100187369
7100193974	7100193976	7100193975	7100194458	7100193983
7100194478				

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	1 - 5

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/internatio 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

Ingredient	CAS Nbr	EC No.	% by Wt	Classification
Silane treated ceramic	444758-98-9		40 - 70	Substance not classified as hazardous
Aromatic urethane dimethacrylate	1431303-59-1		10 - 30	Substance not classified as hazardous
Ytterbium Fluoride	13760-80-0	237-354-2	1 - 10	Substance with a Community level exposure limit in the workplace
Urethane dimethacrylate (UDMA)	72869-86-4	276-957-5	1 - 10	Aquatic Chronic 3, H412 Skin Sens. 1B, H317
Ceramic powder	None		1 - 5	Substance not classified as hazardous
Water	7732-18-5	231-791-2	1 - 5	Substance not classified as hazardous
Aliphatic dimethacrylate	72829-09-5	276-900-4	1 - 5	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 - 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	Condition
Carbon monoxide.	During combustion.
Carbon dioxide.	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
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	CAS Nbr	Agency	Limit type	Additional comments
Fluorides	13760-80-0	UK HSC	TWA(as F):2.5 mg/m3	

UK HSC : UK Health and Safety Commission
TWA: Time-Weighted-Average
STEL: Short Term Exposure Limit
CEIL: Ceiling

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	Tooth
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
Water solubility	Negligible
Viscosity	*No data available.*
Density	1.9 g/cm3

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.
High shear and high temperature conditions

10.5 Incompatible materials
Strong oxidising 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 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
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 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

Name	Route	Species	Value
Overall product	Dermal		No data available; calculated ATE >5,000 mg/kg
Overall product	Ingestion		No data available; calculated ATE2,000 - 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	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Ytterbium Fluoride	Ingestion	Rat	LD50 > 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
Silane treated silica	Dermal		LD50 estimated to be > 5,000 mg/kg
Silane treated silica	Ingestion		LD50 estimated to be > 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
Ceramic powder	Dermal		LD50 estimated to be > 5,000 mg/kg
Ceramic powder	Ingestion		LD50 estimated to be 2,000 - 5,000 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

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

Serious Eye Damage/Irritation

Name	Species	Value
Silane treated ceramic	similar compounds	Mild irritant
Ytterbium Fluoride	Professional judgement	Mild irritant
Silane treated silica	Professional judgement	No significant irritation
Ceramic powder	Rabbit	Mild irritant

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
Ceramic powder	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
Ceramic powder	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	
Ceramic powder	Inhalation	pulmonary fibrosis	Not classified	Multiple animal species	NOAEL Not available	
Ceramic powder	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	Green algae	Endpoint not reached	72 hours	Effect Growth Rate Conc 50%	>100 mg/l
Urethane dimethacrylate (UDMA)	72869-86-4	Water flea	Experimental	48 hours	EC50	>100 mg/l
Urethane dimethacrylate (UDMA)	72869-86-4	Zebra Fish	Experimental	96 hours	LC50	10.1 mg/l
Urethane dimethacrylate (UDMA)	72869-86-4	Green algae	Endpoint not reached	72 hours	Effect Conc. 10% - Growth Rate	>100 mg/l
Ytterbium Fluoride	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
Ceramic powder	None		Data not available or insufficient for classification			
Silane treated silica	248596-91-0		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 availbl-insufficient			N/A	
Aromatic urethane dimethacrylate	1431303-59-1	Data not availbl-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 Fluoride	13760-80-0	Data not availbl-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
Ceramic powder	None	Data not availbl-insufficient			N/A	
Silane treated silica	248596-91-0	Data not availbl-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 Fluoride	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
Ceramic powder	None	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Silane treated silica	248596-91-0	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

70-2014-0689-2

70-2014-0699-1, 70-2014-0700-7, 70-2014-0701-5, 70-2014-0702-3,
70-2014-0703-1, 70-2014-0704-9, 70-2014-0705-6, 70-2014-0706-4,
70-2014-0707-2, 70-2014-0709-8, 70-2014-0710-6, 70-2014-0711-4,
70-2014-0712-2, 70-2014-0713-0, 70-2014-0714-8, 70-2014-0715-5,
70-2014-0716-3, 70-2014-0717-1, 70-2014-0719-7, 70-2014-0722-1,
70-2014-0723-9, 70-2014-0724-7, 70-2014-0725-4, 70-2014-0726-2,
70-2014-0727-0, 70-2014-0729-6, 70-2014-0730-4, 70-2014-0731-2,
70-2014-0732-0, 70-2014-0733-8, 70-2014-0734-6, 70-2014-0735-3,
70-2014-0736-1, 70-2014-0737-9, 70-2014-0739-5, 70-2014-0740-3,
70-2014-0741-1, 70-2014-0742-9, 70-2014-0743-7, 70-2014-0744-5,
70-2014-0745-2, 70-2014-0746-0, 70-2014-0747-8, 70-2014-0750-2,
70-2014-0751-0, 70-2014-0754-4, 70-2014-0767-6

Not hazardous for transportation

70-2014-0720-5

70-2014-0721-3

70-2014-0749-4

70-2014-0752-8

70-2014-0753-6

70-2014-0765-0

70-2014-0766-8

70-2014-0768-4

70-2014-0769-2

70-2014-0690-0

70-2014-0770-0

70-2014-0691-8

70-2014-0692-6

70-2014-0693-4

70-2014-0694-2

70-2014-0695-9

70-2014-0696-7

70-2014-0697-5

ADR/IATA/IMDG: Not hazardous 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

Safety Information Sheet for Medical Devices

Document group:	40-4251-1	**Version number:**	1.00
Revision date:	25/10/2019	**Supersedes date:**	Initial issue.

Transportation version number: 1.00 (25/10/2019)

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™ Universal Restorative - Shade Pink Opaquer

Product Identification Numbers

70-2014-0698-3	70-2014-0708-0	70-2014-0718-9	70-2014-0728-8	70-2014-0738-7
70-2014-0748-6				
7100186769	7100186777	7100186755	7100186754	7100187394
7100187368				

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	1 - 5

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/internatio 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

Ingredient	CAS Nbr	EC No.	% by Wt	Classification
Silane treated ceramic	444758-98-9		40 - 70	Substance not classified as

				hazardous
Aromatic urethane dimethacrylate	1431303-59-1		10 - 30	Substance not classified as hazardous
Ytterbium fluorid	13760-80-0	237-354-2	1 - 10	Substance with a Community level exposure limit in the workplace
Urethane dimethacrylate (UDMA)	72869-86-4	276-957-5	1 - 10	Aquatic Chronic 3, H412 Skin Sens. 1B, H317
Ceramic powder	None		1 - 5	Substance not classified as hazardous
Water	7732-18-5	231-791-2	1 - 5	Substance not classified as hazardous
Aliphatic dimethacrylate	72829-09-5	276-900-4	1 - 5	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 - 5	Substance not classified as hazardous
Titanium dioxide	13463-67-7	236-675-5	< 0.5	Substance with a Community level exposure limit in the workplace

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	Condition
Carbon monoxide.	During combustion.
Carbon dioxide.	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
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	CAS Nbr	Agency	Limit type	Additional comments
Titanium dioxide	13463-67-7	UK HSC	TWA(Inhalable):10 mg/m3;TWA(respirable):4 mg/m³	
Fluorides	13760-80-0	UK HSC	TWA(as F):2.5 mg/m3	

UK HSC : UK Health and Safety Commission
TWA: Time-Weighted-Average
STEL: Short Term Exposure Limit
CEIL: Ceiling

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	Tooth
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
Water solubility	Negligible
Viscosity	*No data available.*
Density	1.9 g/cm3

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.
High shear and high temperature conditions

10.5 Incompatible materials
Strong oxidising 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 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
Respiratory tract irritation: Signs/symptoms may include cough, sneezing, nasal discharge, headache, hoarseness, and nose and throat pain. May cause additional health effects (see below).

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 diarrhoea.

Additional Health Effects:

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.

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 ATE2,000 - 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
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
Silane treated silica	Dermal		LD50 estimated to be > 5,000 mg/kg
Silane treated silica	Ingestion		LD50 estimated to be > 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
Ceramic powder	Dermal		LD50 estimated to be > 5,000 mg/kg
Ceramic powder	Ingestion		LD50 estimated to be 2,000 - 5,000 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	Professional judgement	No significant irritation
Ceramic powder	Rabbit	No significant irritation
Titanium dioxide	Rabbit	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
Silane treated ceramic	similar compounds	Mild irritant
Ytterbium fluorid	Professional judgement	Mild irritant
Silane treated silica	Professional judgement	No significant irritation
Ceramic powder	Rabbit	Mild irritant
Titanium dioxide	Rabbit	No significant irritation

Skin Sensitisation

Name	Species	Value
Silane treated ceramic	similar compounds	Not classified
Urethane dimethacrylate (UDMA)	Guinea pig	Sensitising
Titanium dioxide	Human and animal	Not classified

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
Ceramic powder	In Vitro	Some positive data exist, but the data are not sufficient for classification

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
Ceramic powder	Inhalation	Multiple animal species	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
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	
Ceramic powder	Inhalation	pulmonary fibrosis	Not classified	Multiple animal species	NOAEL Not available	
Ceramic powder	Inhalation	respiratory system	Not classified	Human	NOAEL Not available	occupational exposure
Titanium dioxide	Inhalation	respiratory system	Some positive data exist, but the data are not sufficient for classification	Rat	LOAEL 0.01 mg/l	2 years
Titanium dioxide	Inhalation	pulmonary fibrosis	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	Green algae	Endpoint not reached	72 hours	Effect Growth Rate Conc 50%	>100 mg/l
Urethane dimethacrylate (UDMA)	72869-86-4	Water flea	Experimental	48 hours	EC50	>100 mg/l
Urethane dimethacrylate (UDMA)	72869-86-4	Zebra Fish	Experimental	96 hours	LC50	10.1 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
Ceramic powder	None		Data not available or insufficient for classification			
Silane treated silica	248596-91-0		Data not available or insufficient for classification			
Titanium dioxide	13463-67-7	Diatom	Experimental	72 hours	EC50	>10,000 mg/l
Titanium dioxide	13463-67-7	Fathead minnow	Experimental	96 hours	LC50	>100 mg/l
Titanium dioxide	13463-67-7	Water flea	Experimental	48 hours	EC50	>100 mg/l
Titanium dioxide	13463-67-7	Diatom	Experimental	72 hours	NOEC	5,600 mg/l

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Silane treated ceramic	444758-98-9	Data not availbl-insufficient			N/A	
Aromatic urethane dimethacrylate	1431303-59-1	Data not availbl-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 availbl-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
Ceramic powder	None	Data not availbl-insufficient			N/A	
Silane treated silica	248596-91-0	Data not availbl-insufficient			N/A	
Titanium dioxide	13463-67-7	Data not availbl-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
Ceramic powder	None	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Silane treated silica	248596-91-0	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Titanium dioxide	13463-67-7	Experimental BCF-Carp	42 days	Bioaccumulation factor	9.6	Other methods

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

70-2014-0698-3

70-2014-0708-0, 70-2014-0728-8, 70-2014-0738-7, 70-2014-0748-6

Not hazardous for transportation

70-2014-0718-9

SECTION 15: Regulatory information

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

Carcinogenicity
Contact the manufacturer for more information

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