Safety Information Sheet for Medical Devices

Document group:	30-3992-2	**Version number:**	1.00
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Transportation version number: 1.00 (21/01/2020)

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

FILTEK™ BULK FILL FLOWABLE RESTORATIVE

Product Identification Numbers

70-2014-0039-0	70-2014-0040-8	70-2014-0041-6	70-2014-0042-4	70-2014-0051-5
70-2014-0052-3	70-2014-0053-1	70-2014-0054-9	70-2014-0056-4	70-2014-0060-6
70-2014-0829-4	70-2014-0830-2	70-2014-0831-0	70-2014-0832-8	70-2014-0834-4
70-2014-0835-1	70-2014-0836-9	70-2014-0837-7	70-2014-0839-3	70-2014-0840-1
70-2014-0841-9	70-2014-0842-7	70-2014-0868-2	70-2014-0869-0	70-2014-0871-6
70-2014-0938-3	70-2014-0939-1	70-2014-0940-9	70-2014-0941-7	70-2014-0944-1
70-2014-0954-0	70-2014-0955-7	70-2014-0956-5	70-2014-0957-3	70-2014-1087-8
70-2014-1088-6	70-2014-1089-4	70-2014-1090-2	70-2014-1091-0	70-2014-1092-8
70-2014-1093-6	70-2014-1094-4	70-2014-1156-1	70-2014-1300-5	70-2014-1301-3
70-2014-1302-1	70-2014-1303-9	70-2014-1304-7	70-2014-1305-4	70-2014-1306-2
70-2014-1307-0	70-2014-1308-8	70-2014-1309-6		

7100036588	7100036668	7100036669	7100036670	7100038838
7100038839	7100038860	7100038861	7100036671	7100038863
7100156373	7100156376	7100156377	7100156374	7100156418
7100156417	7100156427	7100156416	7100156428	7100156419
7100141225	7100141226	7100141207	7100141223	7100141210
7100141221	7100141184	7100141185	7100141186	7100219137
7100219138	7100219139	7100219140	7100219142	7100219384
7100219360	7100219485	7100219361	7100219141	7100219377
7100219362	7100219373	7100219374	7100219383	7100219535
7100219522	7100219500	7100219501	7100219499	

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

Identified uses

Medical device; refer to Instructions for Use

Restrictions on Use
For use only by dental professionals

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) respectively Regulation (EU) 2017/745 (MDR), 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 4 - Aquatic Chronic 4; H413

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	10 - 20

HAZARD STATEMENTS:

H317	May cause an allergic skin reaction.
H413	May cause long lasting harmful effects to aquatic life.

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
Carbosilane surfactant		701-308-4	1 - 5	Substance not classified as hazardous
Silane treated ceramic	444758-98-9		50 - 60	Substance not classified as hazardous
Substituted dimethacrylate	27689-12-9	248-607-1	10 - 20	Aquatic Chronic 4, H413
Urethane dimethacrylate (UDMA)	72869-86-4	276-957-5	10 - 20	Aquatic Chronic 3, H412 Skin Sens. 1B, H317
Ytterbium fluorid	13760-80-0	237-354-2	1 - 10	Substance with a Community level exposure limit in the workplace
Dimethacrylate (BIS-MEPP)	41637-38-1	609-946-4	1 - 10	Aquatic Chronic 4, H413
Triethyleneglycol dimenthacrylate (TEGDMA) (REACH Reg. No.:01-2119969287-21)	109-16-0	203-652-6	< 0.2	Skin Sens. 1, H317

Note: Any entry in the EC# column that begins with the numbers 6, 7, 8, or 9 are a Provisional List Number provided by ECHA pending publication of the official EC Inventory Number for the substance.
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
Contain spill. Working from around the edges of the spill inward, cover with bentonite, vermiculite, or commercially available inorganic absorbent material. Mix in sufficient absorbent until it appears dry. Remember, adding an absorbent material does not remove a physical, health, or environmental hazard. Collect as much of the spilled material as possible. Place in a closed container approved for transportation by appropriate authorities. Clean up residue with an appropriate solvent selected by a qualified and authorized person. Ventilate the area with fresh air. Read and follow safety precautions on the solvent label and SIS. 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	Liquid.
Colour	Tooth
Specific Physical Form:	Viscous liquid-like paste
Odor	Slight Acrylate
pH	*Not applicable.*
Boiling point/boiling range	*Not applicable.*
Melting point	*No data available.*
Flammability (solid, gas)	Not applicable.
Explosive properties	Not classified
Oxidising properties	Not classified
Flash point	Flash point > 93 °C (200 °F)
Autoignition temperature	*No data available.*
Flammable Limits(LEL)	*Not applicable.*
Flammable Limits(UEL)	*Not applicable.*
Relative density	1.5 [*Ref Std:*WATER=1]
Water solubility	Negligible
Viscosity	*No data available.*
Density	1.5 g/cm3

9.2. Other information

EU Volatile Organic Compounds	*No data available.*
Molecular weight	*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

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
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

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	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
Substituted dimethacrylate	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Substituted dimethacrylate	Ingestion	Rat	LD50 > 17,600 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
Carbosilane surfactant	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Carbosilane surfactant	Ingestion	Rat	LD50 > 11,700 mg/kg
Dimethacrylate (BIS-MEPP)	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Dimethacrylate (BIS-MEPP)	Ingestion	Rat	LD50 > 2,000 mg/kg
Triethyleneglycol dimenthacrylate (TEGDMA)	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Triethyleneglycol dimenthacrylate (TEGDMA)	Ingestion	Rat	LD50 10,837 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Silane treated ceramic	similar compounds	No significant irritation
Substituted dimethacrylate	Rabbit	No significant irritation
Carbosilane surfactant	Rabbit	No significant irritation
Triethyleneglycol dimenthacrylate (TEGDMA)	Guinea pig	Mild irritant

Serious Eye Damage/Irritation

Name	Species	Value
Silane treated ceramic	similar compounds	Mild irritant
Substituted dimethacrylate	Rabbit	Mild irritant
Ytterbium fluorid	Professional judgement	Mild irritant
Carbosilane surfactant	In vitro data	No significant irritation
Triethyleneglycol dimenthacrylate (TEGDMA)	Professional judgement	Moderate irritant

Skin Sensitisation

Name	Species	Value
Silane treated ceramic	similar compounds	Not classified
Substituted dimethacrylate	Guinea pig	Not classified
Urethane dimethacrylate (UDMA)	Guinea pig	Sensitising
Carbosilane surfactant	Mouse	Not classified
Dimethacrylate (BIS-MEPP)	Guinea pig	Not classified
Triethyleneglycol dimenthacrylate (TEGDMA)	Human and animal	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
Substituted dimethacrylate	In Vitro	Not mutagenic
Carbosilane surfactant	In Vitro	Not mutagenic
Dimethacrylate (BIS-MEPP)	In Vitro	Not mutagenic
Triethyleneglycol dimenthacrylate (TEGDMA)	In Vitro	Some positive data exist, but the data are not sufficient for classification

Carcinogenicity

Name	Route	Species	Value
Silane treated ceramic	Inhalation	similar compounds	Some positive data exist, but the data are not sufficient for classification
Triethyleneglycol dimenthacrylate (TEGDMA)	Dermal	Mouse	Not carcinogenic

Reproductive Toxicity

Reproductive and/or Developmental Effects

Name	Route	Value	Species	Test result	Exposure Duration
Carbosilane surfactant	Ingestion	Not classified for development	Rat	NOAEL 1,000 mg/kg/day	during gestation
Triethyleneglycol dimenthacrylate (TEGDMA)	Ingestion	Not classified for female reproduction	Mouse	NOAEL 1 mg/kg/day	1 generation
Triethyleneglycol dimenthacrylate (TEGDMA)	Ingestion	Not classified for male reproduction	Mouse	NOAEL 1 mg/kg/day	1 generation
Triethyleneglycol dimenthacrylate (TEGDMA)	Ingestion	Not classified for development	Mouse	NOAEL 1 mg/kg/day	1 generation

Target Organ(s)

Specific Target Organ Toxicity - single exposure
For the component/components, either no data 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	
Carbosilane surfactant	Ingestion	endocrine system | hematopoietic system | liver | heart | skin | gastrointestinal tract | bone, teeth, nails, and/or hair | immune system | muscles | nervous system | eyes | kidney and/or bladder | respiratory system | vascular system	Not classified	Rat	NOAEL 1,000 mg/kg/day	90 days
Triethyleneglycol dimenthacrylate (TEGDMA)	Dermal	kidney and/or bladder | blood	Not classified	Mouse	NOAEL 833 mg/kg/day	78 weeks

Aspiration Hazard
For the component/components, either no data 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
Carbosilane surfactant	701-308-4	Green Algae	Endpoint not reached	96 hours		>100 mg/l
Carbosilane surfactant	701-308-4	Water flea	Endpoint not reached	48 hours		>100 mg/l
Carbosilane surfactant	701-308-4	Green Algae	Experimental	96 hours	Effect Concentration 10%	1.1 mg/l
Silane treated ceramic	444758-98-9		Data not available or insufficient for classification			
Substituted dimethacrylate	27689-12-9	Green algae	Experimental	72 hours	EC50	>100 mg/l
Substituted dimethacrylate	27689-12-9	Water flea	Experimental	48 hours	EC50	>100 mg/l
Substituted dimethacrylate	27689-12-9	Green algae	Experimental	72 hours	NOEC	>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	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
Dimethacrylate (BIS-MEPP)	41637-38-1	Green algae	Endpoint not reached	72 hours	EC50	>100 mg/l
Dimethacrylate (BIS-MEPP)	41637-38-1	Green algae	Experimental	72 hours	NOEC	0.05 mg/l
Triethyleneglycol dimenthacrylate (TEGDMA)	109-16-0	Green Algae	Experimental	72 hours	EC50	>100 mg/l
Triethyleneglycol dimenthacrylate (TEGDMA)	109-16-0	Zebra Fish	Experimental	96 hours	LC50	16.4 mg/l
Triethyleneglycol dimenthacrylate (TEGDMA)	109-16-0	Green algae	Experimental	72 hours	NOEC	18.6 mg/l
Triethyleneglycol dimenthacrylate (TEGDMA)	109-16-0	Water flea	Experimental	21 days	NOEC	32 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	
Substituted dimethacrylate	27689-12-9	Experimental Biodegradation	28 days	CO2 evolution	7-12 % weight	OECD 301B - Modified sturm or CO2
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	
Dimethacrylate (BIS-MEPP)	41637-38-1	Estimated Biodegradation	28 days	CO2 evolution	7-12 % weight	OECD 301B - Modified sturm or CO2
Triethyleneglycol dimenthacrylate (TEGDMA)	109-16-0	Experimental Biodegradation	28 days	CO2 evolution	85 % weight	OECD 301B - Modified sturm or CO2

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
Substituted dimethacrylate	27689-12-9	Estimated Bioconcentration		Log Kow	7.61	Estimated: Octanol-water partition coefficient
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
Dimethacrylate (BIS-MEPP)	41637-38-1	Estimated Bioconcentration		Bioaccumulation factor	6.6	Estimated: Bioconcentration factor
Triethyleneglycol dimenthacrylate (TEGDMA)	109-16-0	Experimental Bioconcentration		Log Kow	2.3	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

70-2014-0039-0, 70-2014-0040-8, 70-2014-0041-6, 70-2014-0042-4,
70-2014-0051-5, 70-2014-0052-3, 70-2014-0053-1, 70-2014-0054-9,
70-2014-0056-4, 70-2014-0060-6, 70-2014-1087-8, 70-2014-1088-6,
70-2014-1089-4, 70-2014-1090-2, 70-2014-1300-5, 70-2014-1301-3,
70-2014-1302-1, 70-2014-1303-9, 70-2014-1304-7, 70-2014-1305-4,
70-2014-1306-2, 70-2014-1307-0, 70-2014-1308-8, 70-2014-1309-6

Not hazardous for transportation

70-2014-0839-3

70-2014-0840-1

70-2014-0841-9

70-2014-0842-7

70-2014-0868-2

70-2014-0869-0

70-2014-0871-6

70-2014-0938-3

70-2014-0939-1

70-2014-0940-9

70-2014-0829-4

70-2014-0941-7

70-2014-0944-1

70-2014-0954-0

70-2014-0955-7

70-2014-0956-5

70-2014-0957-3

70-2014-1091-0

70-2014-1092-8

70-2014-1093-6

70-2014-1094-4

70-2014-0830-2

70-2014-1156-1

70-2014-0831-0

70-2014-0832-8

70-2014-0834-4

70-2014-0835-1

70-2014-0836-9

70-2014-0837-7

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

H317	May cause an allergic skin reaction.
H412	Harmful to aquatic life with long lasting effects.
H413	May cause long lasting harmful effects to aquatic life.

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