Safety Information Sheet for Medical Devices

Document group:	28-0653-7	**Version number:**	2.00
Revision date:	27/07/2020	**Supersedes date:**	20/07/2020

Transportation version number: 1.00 (27/07/2020)

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™ Z500 Universal Restorative Single Shade Intro Kit (8020TP, 8021TP)

Product Identification Numbers
70-2010-7861-8 70-2010-7870-9

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 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:

28-0649-5

TRANSPORTATION INFORMATION

70-2010-7861-8, 70-2010-7870-9

Not hazardous for transportation

ADR/IMDG/IATA: Not restricted for transport.

KIT LABEL

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

Revision information:
A revision has been performed due to the need to update the safety information for the medical device.

Safety Information Sheet for Medical Devices

Document group:	28-0649-5	**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

8020/8021 3M ESPE Filtek Z500 Universal restorative

Product Identification Numbers

70-2010-7852-7	70-2010-7853-5	70-2010-7854-3	70-2010-7855-0	70-2010-7856-8
70-2010-7857-6	70-2010-7858-4	70-2010-7859-2	70-2010-7860-0	70-2010-7862-6
70-2010-7863-4	70-2010-7864-2	70-2010-7865-9	70-2010-7866-7	70-2010-7867-5
70-2010-7868-3	70-2010-7869-1	70-2010-7871-7	70-2010-7872-5	70-2010-7873-3
7000054510	7000054491	7000054492	7000054493	7000054494
7000054495	7000054496	7000054497	7000054498	7000054499
7000054501	7000054502	7000054503	7000054512	7000054504
7000054505	7000054506	7000054507	7000054508	7000054511

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.
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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

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
Bis-GMA	1565-94-2	216-367-7	1 - 10
Urethane dimethacrylate (UDMA)	72869-86-4	276-957-5	5 - 10
Triethylene glycol dimethacrylate	109-16-0	203-652-6	< 5

HAZARD STATEMENTS:
H317 May cause an allergic skin reaction.

PRECAUTIONARY STATEMENTS

Prevention:
P280E Wear protective gloves.

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

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		60 - 100	Substance not classified as hazardous
Bis-GMA	1565-94-2	216-367-7	1 - 10	Skin Sens. 1B, H317
Silane treated silica	248596-91-0		5 - 10	Substance not classified as hazardous
Urethane dimethacrylate (UDMA)	72869-86-4	276-957-5	5 - 10	Aquatic Chronic 3, H412 Skin Sens. 1B, H317
Dimethacrylate (BIS-MEPP)	41637-38-1	609-946-4	5 - 10	Aquatic Chronic 4, H413
Triethylene glycol dimethacrylate (REACH Reg. No.:01-2119969287-21)	109-16-0	203-652-6	< 5	Skin Sens. 1, H317
Initiator	58109-40-3	261-134-5	< 0.2	Acute Tox. 2, H300

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
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	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 [*Ref Std:*WATER=1]
Water solubility	Negligible
Viscosity	*Not applicable.*
Density	1.9 g/cm3

9.2. Other information

EU Volatile Organic Compounds	*No data available.*
Percent volatile	*Not applicable.*

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
Light.

10.5 Incompatible materials
None known.

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	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
Silane treated silica	Dermal		LD50 estimated to be > 5,000 mg/kg
Silane treated silica	Ingestion		LD50 estimated to be > 5,000 mg/kg
Dimethacrylate (BIS-MEPP)	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Urethane dimethacrylate (UDMA)	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Dimethacrylate (BIS-MEPP)	Ingestion	Rat	LD50 > 2,000 mg/kg
Urethane dimethacrylate (UDMA)	Ingestion	Rat	LD50 > 5,000 mg/kg
Bis-GMA	Ingestion		LD50 estimated to be 2,000 - 5,000 mg/kg
Bis-GMA	Dermal	Professional judgement	LD50 estimated to be 2,000 - 5,000 mg/kg
Triethylene glycol dimethacrylate	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Triethylene glycol dimethacrylate	Ingestion	Rat	LD50 10,837 mg/kg
Initiator	Ingestion	Rat	LD50 32 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
Bis-GMA	Not available	Minimal irritation
Triethylene glycol dimethacrylate	Guinea pig	Mild irritant
Initiator	Rabbit	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
Silane treated ceramic	similar compounds	Mild irritant
Silane treated silica	Professional judgement	No significant irritation
Bis-GMA	Not available	Moderate irritant
Triethylene glycol dimethacrylate	Professional judgement	Moderate irritant
Initiator	Rabbit	Mild irritant

Skin Sensitisation

Name	Species	Value
Silane treated ceramic	similar compounds	Not classified
Dimethacrylate (BIS-MEPP)	Guinea pig	Not classified
Urethane dimethacrylate (UDMA)	Guinea pig	Sensitising
Bis-GMA	Guinea pig	Sensitising
Triethylene glycol dimethacrylate	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
Dimethacrylate (BIS-MEPP)	In Vitro	Not mutagenic
Bis-GMA	In Vitro	Some positive data exist, but the data are not sufficient for classification
Triethylene glycol dimethacrylate	In Vitro	Some positive data exist, but the data are not sufficient for classification
Initiator	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
Triethylene glycol dimethacrylate	Dermal	Mouse	Not carcinogenic

Reproductive Toxicity

Reproductive and/or Developmental Effects

Name	Route	Value	Species	Test result	Exposure Duration
Bis-GMA	Ingestion	Not classified for female reproduction	Mouse	NOAEL 0.8 mg/kg/day	premating & during gestation
Bis-GMA	Ingestion	Not classified for male reproduction	Mouse	NOAEL 0.8 mg/kg/day	premating & during gestation
Bis-GMA	Ingestion	Not classified for development	Mouse	NOAEL 0.8 mg/kg/day	premating & during gestation
Triethylene glycol dimethacrylate	Ingestion	Not classified for female reproduction	Mouse	NOAEL 1 mg/kg/day	1 generation
Triethylene glycol dimethacrylate	Ingestion	Not classified for male reproduction	Mouse	NOAEL 1 mg/kg/day	1 generation
Triethylene glycol dimethacrylate	Ingestion	Not classified for development	Mouse	NOAEL 1 mg/kg/day	1 generation

Target Organ(s)

Specific Target Organ Toxicity - single exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Initiator	Inhalation	respiratory irritation	Not classified	Not available	Irritation Equivocal	

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	
Bis-GMA	Ingestion	endocrine system | liver | nervous system | kidney and/or bladder	Not classified	Mouse	NOAEL 0.8 mg/kg/day	premating & during gestation
Triethylene glycol dimethacrylate	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
Silane treated ceramic	444758-98-9		Data not available or insufficient for classification			
Bis-GMA	1565-94-2		Data not available or insufficient for classification			
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
Silane treated silica	248596-91-0		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

Triethylene glycol dimethacrylate	109-16-0	Green Algae	Experimental	72 hours	EC50	>100 mg/l
Triethylene glycol dimethacrylate	109-16-0	Zebra Fish	Experimental	96 hours	LC50	16.4 mg/l
Triethylene glycol dimethacrylate	109-16-0	Green algae	Experimental	72 hours	NOEC	18.6 mg/l
Triethylene glycol dimethacrylate	109-16-0	Water flea	Experimental	21 days	NOEC	32 mg/l
Initiator	58109-40-3	Water flea	Experimental	48 hours	EC50	9.5 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	
Bis-GMA	1565-94-2	Estimated Biodegradation	28 days	BOD	32 % weight	OECD 301C - MITI test (I)
Dimethacrylate (BIS-MEPP)	41637-38-1	Estimated Biodegradation	28 days	CO2 evolution	7-12 % weight	OECD 301B - Modified sturm or CO2
Silane treated silica	248596-91-0	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
Triethylene glycol dimethacrylate	109-16-0	Experimental Biodegradation	28 days	CO2 evolution	85 % weight	OECD 301B - Modified sturm or CO2
Initiator	58109-40-3	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
Bis-GMA	1565-94-2	Estimated Bioconcentration		Bioaccumulation factor	5.8	Estimated: Bioconcentration factor
Dimethacrylate (BIS-MEPP)	41637-38-1	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
Urethane dimethacrylate (UDMA)	72869-86-4	Experimental Bioconcentration		Log Kow	3.39	Other methods
Triethylene glycol dimethacrylate	109-16-0	Experimental Bioconcentration		Log Kow	2.3	Other methods
Initiator	58109-40-3	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.

EU waste code (product container after use)
180107 Chemicals other than those mentioned in 18 01 06

SECTION 14: Transportation information

70-2010-7852-7, 70-2010-7853-5, 70-2010-7854-3, 70-2010-7855-0,
70-2010-7856-8, 70-2010-7857-6, 70-2010-7858-4, 70-2010-7859-2,
70-2010-7860-0, 70-2010-7862-6, 70-2010-7863-4, 70-2010-7864-2,
70-2010-7865-9, 70-2010-7866-7, 70-2010-7867-5, 70-2010-7868-3,
70-2010-7869-1, 70-2010-7871-7, 70-2010-7872-5, 70-2010-7873-3

Not hazardous for transportation

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

H300	Fatal if swallowed.
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