Safety Information Sheet for Medical Devices

Document group:	16-0386-9	**Version number:**	1.00
Revision date:	16/10/2019	**Supersedes date:**	Initial issue.

Transportation version number: 1.00 (16/10/2019)

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 Clinpro Sealant

Product Identification Numbers
LE-F100-2466-4

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), 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
Triethylene glycol dimethacrylate	109-16-0	203-652-6	40 - 50
Bis-GMA	1565-94-2	216-367-7	40 - 50

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
Triethylene glycol dimethacrylate (REACH Reg. No.:01-2119969287-21)	109-16-0	203-652-6	40 - 50	Skin Sens. 1, H317
Bis-GMA	1565-94-2	216-367-7	40 - 50	Skin Sens. 1B, H317
Silane treated silica	68611-44-9	271-893-4	5 - 10	Substance with a Community level exposure limit in the workplace
Tetrabutylammonium tetrafluoroborate	429-42-5	207-058-8	< 5	Substance not classified as hazardous
Initiator	58109-40-3	261-134-5	< 1	Acute Tox. 2, H300
Triethylene glycol dimethacrylate	603-36-1	210-037-6	< 0.5	Acute Tox. 4, H332 - Nota 1,A

				Acute Tox. 3, H301
Aromatic amine	10287-53-3	233-634-3	< 0.5	Aquatic Chronic 2, H411
Titanium dioxide (REACH Reg. No.:01-2119489379-17)	13463-67-7	236-675-5	< 0.5	Substance with a Community level exposure limit in the workplace
Hydroquinone	123-31-9	204-617-8	< 0.05	Acute Tox. 4, H302; Eye Dam. 1, H318; Skin Sens. 1B, H317; Muta. 2, H341; Carc. 2, H351; Aquatic Acute 1, H400,M=10

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. Collect as much of the spilled material as possible. Place in a closed container approved for transportation by appropriate authorities. 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
Hydroquinone	123-31-9	UK HSC	TWA: 0.5 mg/m³	
Titanium dioxide	13463-67-7	UK HSC	TWA(Inhalable):10 mg/m3;TWA(respirable):4 mg/m³	
Antimony trioxide	603-36-1	UK HSC	TWA(as Sb):0.5 mg/m3	
Silicon dioxide	68611-44-9	UK HSC	TWA(as inhalable dust):6 mg/m3;TWA(as respirable dust):2.4 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	Transparent Yellow
Specific Physical Form:	Liquid.
Odor	Characteristic Odour
pH	*No data available.*
Boiling point/boiling range	*No data available.*
Melting point	*Not applicable.*
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)	*No data available.*
Flammable Limits(UEL)	*No data available.*
Relative density	1.2 [*Ref Std:*WATER=1]
Water solubility	*No data available.*
Viscosity	approximately 1,000 mm²/sec
Density	1.2 g/ml

9.2. Other information

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

SECTION 10: Stability and reactivity

10.1 Reactivity
This material is considered to be non reactive under normal use conditions

10.2 Chemical stability
Stable.

10.3 Possibility of hazardous reactions
Hazardous polymerisation will not occur.

10.4 Conditions to avoid
None known.

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
Mild Skin Irritation: Signs/symptoms may include localised redness, swelling, itching, and dryness. Allergic skin reaction (non-photo induced): Signs/symptoms may include redness, swelling, blistering, and itching.

Eye contact
Moderate eye irritation: Signs/symptoms may include redness, swelling, pain, tearing, and blurred or hazy vision.

Ingestion
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	Ingestion	Rat	LD50 > 5,000 mg/kg
Overall product	Dermal	similar health hazards	LD50 Not available
Triethylene glycol dimethacrylate	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Triethylene glycol dimethacrylate	Ingestion	Rat	LD50 10,837 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
Silane treated silica	Dermal	Rabbit	LD50 > 5,000 mg/kg
Silane treated silica	Inhalation-Dust/Mist (4	Rat	LC50 > 0.691 mg/l

	hours)		
Silane treated silica	Ingestion	Rat	LD50 > 5,110 mg/kg
Initiator	Ingestion	Rat	LD50 32 mg/kg
Triethylene glycol dimethacrylate	Inhalation-Dust/Mist		LC50 estimated to be 1 - 5 mg/l
Triethylene glycol dimethacrylate	Dermal	Rat	LD50 > 2,000 mg/kg
Triethylene glycol dimethacrylate	Ingestion	Rat	LD50 82.5 mg/kg
Aromatic amine	Dermal	Rat	LD50 > 2,000 mg/kg
Aromatic amine	Ingestion	Rat	LD50 > 2,000 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
Hydroquinone	Dermal	Rat	LD50 > 4,800 mg/kg
Hydroquinone	Ingestion	Rat	LD50 302 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Triethylene glycol dimethacrylate	Guinea pig	Mild irritant
Bis-GMA	Not available	Minimal irritation
Silane treated silica	Rabbit	No significant irritation
Initiator	Rabbit	No significant irritation
Triethylene glycol dimethacrylate	Rabbit	Minimal irritation
Aromatic amine	Rabbit	No significant irritation
Titanium dioxide	Rabbit	No significant irritation
Hydroquinone	Human and animal	Minimal irritation

Serious Eye Damage/Irritation

Name	Species	Value
Triethylene glycol dimethacrylate	Professional judgement	Moderate irritant
Bis-GMA	Not available	Moderate irritant
Silane treated silica	Rabbit	No significant irritation
Initiator	Rabbit	Mild irritant
Triethylene glycol dimethacrylate	Rabbit	Mild irritant
Aromatic amine	Rabbit	Mild irritant
Titanium dioxide	Rabbit	No significant irritation
Hydroquinone	Human	Corrosive

Skin Sensitisation

Name	Species	Value
Triethylene glycol dimethacrylate	Human and animal	Sensitising
Bis-GMA	Guinea pig	Sensitising
Silane treated silica	Human and animal	Not classified
Titanium dioxide	Human and animal	Not classified
Hydroquinone	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
Triethylene glycol dimethacrylate	In Vitro	Some positive data exist, but the data are not sufficient for classification
Bis-GMA	In Vitro	Some positive data exist, but the data are not sufficient for classification
Silane treated silica	In Vitro	Not mutagenic
Initiator	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
Hydroquinone	In Vitro	Some positive data exist, but the data are not sufficient for classification
Hydroquinone	In vivo	Some positive data exist, but the data are not sufficient for classification

Carcinogenicity

Name	Route	Species	Value
Triethylene glycol dimethacrylate	Dermal	Mouse	Not carcinogenic
Silane treated silica	Not specified.	Mouse	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.
Hydroquinone	Dermal	Mouse	Not carcinogenic
Hydroquinone	Ingestion	Multiple animal species	Some positive data exist, but the data are not sufficient for classification

Reproductive Toxicity

Reproductive and/or Developmental Effects

Name	Route	Value	Species	Test result	Exposure Duration
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
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
Silane treated silica	Ingestion	Not classified for female reproduction	Rat	NOAEL 509 mg/kg/day	1 generation
Silane treated silica	Ingestion	Not classified for male reproduction	Rat	NOAEL 497 mg/kg/day	1 generation
Silane treated silica	Ingestion	Not classified for development	Rat	NOAEL 1,350 mg/kg/day	during organogenesis
Hydroquinone	Ingestion	Not classified for female reproduction	Rat	NOAEL 150 mg/kg/day	2 generation
Hydroquinone	Ingestion	Not classified for male reproduction	Rat	NOAEL 150 mg/kg/day	2 generation
Hydroquinone	Ingestion	Not classified for development	Rat	NOAEL 100 mg/kg/day	during organogenesis

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	
Hydroquinone	Ingestion	nervous system	May cause damage to organs	Rat	NOAEL Not available	not applicable
Hydroquinone	Ingestion	kidney and/or bladder	Not classified	Rat	NOAEL 400 mg/kg	not applicable

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Triethylene glycol dimethacrylate	Dermal	kidney and/or bladder | blood	Not classified	Mouse	NOAEL 833 mg/kg/day	78 weeks
Bis-GMA	Ingestion	endocrine system | liver | nervous system | kidney	Not classified	Mouse	NOAEL 0.8 mg/kg/day	premating & during gestation

		and/or bladder				
Silane treated silica	Inhalation	respiratory system | silicosis	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
Hydroquinone	Ingestion	blood	Not classified	Rat	NOAEL Not available	40 days
Hydroquinone	Ingestion	bone marrow | liver	Not classified	Rat	NOAEL Not available	9 weeks
Hydroquinone	Ingestion	kidney and/or bladder	Not classified	Rat	LOAEL 50 mg/kg/day	15 months
Hydroquinone	Ocular	eyes	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
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
Bis-GMA	1565-94-2		Data not available or insufficient for classification			
Silane treated silica	68611-44-9		Data not available or insufficient for classification			
Tetrabutylammonium tetrafluoroborate	429-42-5		Data not available or insufficient for classification			
Initiator	58109-40-3	Water flea	Experimental	48 hours	EC50	9.5 mg/l
Triethylene glycol dimethacrylate	603-36-1		Data not available or insufficient for classification			
Aromatic amine	10287-53-3	Green Algae	Experimental	72 hours	EC50	2.8 mg/l

Aromatic amine	10287-53-3	Rainbow trout	Experimental	96 hours	LC50	1.9 mg/l
Aromatic amine	10287-53-3	Water flea	Experimental	48 hours	EC50	4.5 mg/l
Aromatic amine	10287-53-3	Green Algae	Experimental	72 hours	Effect Conc. 10% - Growth Rate	0.71 mg/l
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
Hydroquinone	123-31-9	Green algae	Experimental	72 hours	EC50	0.053 mg/l
Hydroquinone	123-31-9	Rainbow trout	Experimental	96 hours	LC50	0.044 mg/l
Hydroquinone	123-31-9	Water flea	Experimental	48 hours	EC50	0.061 mg/l
Hydroquinone	123-31-9	Fathead minnow	Experimental	32 days	NOEC	>=0.066 mg/l
Hydroquinone	123-31-9	Green Algae	Experimental	72 hours	NOEC	0.0015 mg/l
Hydroquinone	123-31-9	Water flea	Experimental	21 days	NOEC	0.0029 mg/l

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Triethylene glycol dimethacrylate	109-16-0	Experimental Biodegradation	28 days	CO2 evolution	85 % weight	OECD 301B - Modified sturm or CO2
Bis-GMA	1565-94-2	Estimated Biodegradation	28 days	BOD	32 % weight	OECD 301C - MITI test (I)
Silane treated silica	68611-44-9	Data not availbl-insufficient			n/a	
Tetrabutylammonium tetrafluoroborate	429-42-5	Data not availbl-insufficient			N/A	
Initiator	58109-40-3	Data not availbl-insufficient			N/A	
Triethylene glycol dimethacrylate	603-36-1	Estimated Biodegradation	28 days	BOD	<20 % weight	OECD 301F - Manometric respirometry
Aromatic amine	10287-53-3	Experimental Biodegradation	28 days	CO2 evolution	40 %CO2 evolution/THCO2 evolution	OECD 301B - Modified sturm or CO2
Titanium dioxide	13463-67-7	Data not availbl-insufficient			N/A	
Hydroquinone	123-31-9	Experimental Biodegradation	14 days	BOD	70 % BOD/ThBOD	OECD 301C - MITI test (I)

12.3 : Bioaccumulative potential

Material	Cas No.	Test type	Duration	Study Type	Test result	Protocol
Triethylene glycol dimethacrylate	109-16-0	Experimental Bioconcentration		Log Kow	2.3	Other methods
Bis-GMA	1565-94-2	Estimated Bioconcentration		Bioaccumulation factor	5.8	Estimated: Bioconcentration factor
Silane treated silica	68611-44-9	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Tetrabutylammonium tetrafluoroborate	429-42-5	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Initiator	58109-40-3	Data not available or insufficient for	N/A	N/A	N/A	N/A

		classification				
Triethylene glycol dimethacrylate	603-36-1	Estimated Bioconcentration		Log Kow	6.02	Estimated: Octanol-water partition coefficient
Aromatic amine	10287-53-3	Experimental Bioconcentration		Log Kow	3.2	Other methods
Titanium dioxide	13463-67-7	Experimental BCF-Carp	42 days	Bioaccumulation factor	9.6	Other methods
Hydroquinone	123-31-9	Experimental Bioconcentration		Log Kow	0.59	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

ADR/IATA/IMDG: Not restricted for transport.

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

H300	Fatal if swallowed.
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H332	Harmful if inhaled.
H341	Suspected of causing genetic defects.

H351	Suspected of causing cancer.
H400	Very toxic to aquatic life.
H411	Toxic 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:	29-8286-6	**Version number:**	2.00
Revision date:	12/08/2021	**Supersedes date:**	16/10/2019

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™ Scotchbond™ Universal Etchant (41263)

Product Identification Numbers

70-2011-3906-3	70-2011-4006-1	70-2011-4007-9	70-2011-4411-3	70-2011-4412-1
70-2011-4413-9				
7000055181	7000055191	7100007505	7100048580	7100048585
7100048586				

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

The health and environmental classifications of this material have been derived using the calculation method, except in cases where test data are available or the physical form impacts classification. Classification(s) based on test data or physical form are noted below, if applicable.

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:
Substance or Mixture Corrosive to Metals, Category 1 - Met. Corr. 1; H290
Skin Corrosion/Irritation, Category 1B - Skin Corr. 1B; H314
Serious Eye Damage/Eye Irritation, Category 1 - Eye Dam. 1; H318

For full text of H phrases, see Section 16.

2.2. Label elements
CLP REGULATION (EC) No 1272/2008

SIGNAL WORD
DANGER.

Symbols
GHS05 (Corrosion) |

Pictograms

Ingredients:

Ingredient	CAS Nbr	EC No.	% by Wt
Phosphoric acid	7664-38-2	231-633-2	30 - 40

HAZARD STATEMENTS:

H290	May be corrosive to metals.
H314	Causes severe skin burns and eye damage.

PRECAUTIONARY STATEMENTS

Prevention:

P280D	Wear protective gloves, protective clothing, and eye/face protection.

Response:

P303 + P361 + P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTRE or doctor/physician.

Notes on labelling

P260 not applied since the product is a gel, with no potential for inhalation exposure.

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

3.1. Substances
Not applicable

3.2. Mixtures

Ingredient	Identifier(s)	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Water	(CAS-No.) 7732-18-5 (EC-No.) 231-791-2	50 - 65	Substance not classified as hazardous
Phosphoric acid	(CAS-No.) 7664-38-2 (EC-No.) 231-633-2	30 - 40	Skin Corr. 1B, H314 Eye Dam. 1, H318 Nota B Met. Corr. 1, H290 Acute Tox. 4, H302
Silica	(CAS-No.) 112945-52-5	5 - 10	Substance with a national occupational exposure limit
Polyglycol	(CAS-No.) 25322-68-3	1 - 5	Substance not classified as hazardous
Aluminum oxide	(CAS-No.) 1344-28-1 (EC-No.) 215-691-6	< 2	Substance with a national occupational exposure limit

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

Specific Concentration Limits

Ingredient	Identifier(s)	Specific Concentration Limits
Phosphoric acid	(CAS-No.) 7664-38-2 (EC-No.) 231-633-2	(C >= 25%) Skin Corr. 1B, H314 (10% =< C < 25%) Skin Irrit. 2, H315 (C >= 25%) Eye Dam. 1, H318 (10% =< C < 25%) Eye Irrit. 2, H319

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 flush with large amounts of water for at least 15 minutes. Remove contaminated clothing. Get immediate medical attention. Wash clothing before reuse.

Eye contact
Immediately flush with large amounts of water for at least 15 minutes. Remove contact lenses if easy to do. Continue rinsing. Immediately get medical attention.

If swallowed
Rinse mouth. Do not induce vomiting. Get immediate 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. For large spills, if necessary, get assistance from professional spill clean up team. For small spills, carefully cover the spill with soda ash (sodium carbonate) or sodium bicarbonate. Work from around the perimeter inward. Avoid splashing. Add enough water to ease mixing and stir. Continue stirring and adding water and neutralizing agent until the reaction stops. Let cool before collecting. Or use a commercially available 'Acid spill' clean-up kit. Follow the kit directions exactly, as specified. 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 metal container approved for use in transportation by appropriate authorities. The container must be lined with polyethylene plastic or contain a plastic drum liner made of polyethylene. Clean up residue with water. Cover, but do not seal for 48 hours. 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
Silicon dioxide	112945-52-5	UK HSC	TWA(as respirable dust):2.4 mg/m3;TWA(as inhalable	

			dust):6 mg/m3
Aluminum oxide	1344-28-1	UK HSC	TWA(as respirable dust):4 mg/m3;TWA(as inhalable dust):10 mg/m3
Phosphoric acid	7664-38-2	UK HSC	TWA:1 mg/m3;STEL:2 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

Physical state	Liquid.
Specific Physical Form:	Gel
Colour	Blue
Odor	Slight Odor, Characteristic Odour
Melting point/freezing point	*Not applicable.*
Boiling point/boiling range	*No data available.*
Flammability (solid, gas)	Not applicable.
Flammable Limits(LEL)	*No data available.*
Flammable Limits(UEL)	*No data available.*
Flash point	> 100 ºC [*Test Method:*Closed Cup]
Autoignition temperature	*No data available.*
Relative density	1.1 - 1.2 [*Ref Std:*WATER=1]
pH	< 1
Kinematic Viscosity	*No data available.*
Water solubility	Complete
Density	1.1 g/ml - 1.2 g/ml

9.2. Other information

9.2.2 Other safety characteristics

EU Volatile Organic Compounds	*No data available.*
Evaporation rate	*No data available.*
Molecular weight	*No data available.*
Percent volatile	*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 bases.

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 internal hazard assessments.

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

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
Corrosive (skin burns): Signs/symptoms may include localised redness, swelling, itching, intense pain, blistering, ulceration, and tissue destruction.

Eye contact
Corrosive (eye burns): Signs/symptoms may include cloudy appearance of the cornea, chemical burns, severe pain, tearing,

ulcerations, significantly impaired vision or complete loss of vision.

Ingestion
Gastrointestinal corrosion: Signs/symptoms may include severe mouth, throat and abdominal pain, nausea, vomiting, and diarrhea; blood in the faeces and/or vomitus may also be seen.

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 ATE >5,000 mg/kg
Phosphoric acid	Dermal	Rabbit	LD50 2,740 mg/kg
Phosphoric acid	Ingestion	Rat	LD50 1,530 mg/kg
Silica	Dermal	Rabbit	LD50 > 5,000 mg/kg
Silica	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 0.691 mg/l
Silica	Ingestion	Rat	LD50 > 5,110 mg/kg
Polyglycol	Dermal	Rabbit	LD50 > 20,000 mg/kg
Polyglycol	Ingestion	Rat	LD50 32,770 mg/kg
Aluminum oxide	Dermal		LD50 estimated to be > 5,000 mg/kg
Aluminum oxide	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 2.3 mg/l
Aluminum oxide	Ingestion	Rat	LD50 > 5,000 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Phosphoric acid	Rabbit	Corrosive
Silica	Rabbit	No significant irritation
Polyglycol	Rabbit	Minimal irritation
Aluminum oxide	Rabbit	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
Phosphoric acid	official classification	Corrosive
Silica	Rabbit	No significant irritation
Polyglycol	Rabbit	Mild irritant
Aluminum oxide	Rabbit	No significant irritation

Skin Sensitisation

Name	Species	Value
Phosphoric acid	Human	Not classified
Silica	Human and animal	Not classified
Polyglycol	Guinea pig	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
Phosphoric acid	In Vitro	Not mutagenic
Silica	In Vitro	Not mutagenic
Polyglycol	In Vitro	Not mutagenic

Polyglycol	In vivo	Not mutagenic
Aluminum oxide	In Vitro	Not mutagenic

Carcinogenicity

Name	Route	Species	Value
Silica	Not specified.	Mouse	Some positive data exist, but the data are not sufficient for classification
Polyglycol	Ingestion	Rat	Not carcinogenic
Aluminum oxide	Inhalation	Rat	Not carcinogenic

Reproductive Toxicity

Reproductive and/or Developmental Effects

Name	Route	Value	Species	Test result	Exposure Duration
Phosphoric acid	Ingestion	Not classified for female reproduction	Rat	NOAEL 750 mg/kg/day	2 generation
Phosphoric acid	Ingestion	Not classified for male reproduction	Rat	NOAEL 750 mg/kg/day	2 generation
Phosphoric acid	Ingestion	Not classified for development	Rat	NOAEL 750 mg/kg/day	2 generation
Silica	Ingestion	Not classified for female reproduction	Rat	NOAEL 509 mg/kg/day	1 generation
Silica	Ingestion	Not classified for male reproduction	Rat	NOAEL 497 mg/kg/day	1 generation
Silica	Ingestion	Not classified for development	Rat	NOAEL 1,350 mg/kg/day	during organogenesis
Polyglycol	Ingestion	Not classified for female reproduction	Rat	NOAEL 1,125 mg/kg/day	during gestation
Polyglycol	Ingestion	Not classified for male reproduction	Rat	NOAEL 5699 +/- 1341 mg/kg/day	5 days
Polyglycol	Not specified.	Not classified for reproduction and/or development		NOEL N/A	
Polyglycol	Ingestion	Not classified for development	Mouse	NOAEL 562 mg/animal/day	during gestation

Target Organ(s)

Specific Target Organ Toxicity - single exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Phosphoric acid	Inhalation	respiratory irritation	Some positive data exist, but the data are not sufficient for classification	Human	NOAEL Not available	occupational exposure
Polyglycol	Inhalation	respiratory irritation	Not classified	Rat	NOAEL 1.008 mg/l	2 weeks

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Silica	Inhalation	respiratory system | silicosis	Not classified	Human	NOAEL Not available	occupational exposure
Polyglycol	Inhalation	respiratory system	Not classified	Rat	NOAEL 1.008 mg/l	2 weeks
Polyglycol	Ingestion	kidney and/or bladder | heart | endocrine system | hematopoietic system | liver | nervous system	Not classified	Rat	NOAEL 5,640 mg/kg/day	13 weeks
Aluminum oxide	Inhalation	pneumoconiosis	Some positive data exist, but the data are not sufficient for classification	Human	NOAEL Not available	occupational exposure
Aluminum oxide	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.

11.2. Information on other hazards

This material does not contain any substances that are assessed to be an endocrine disruptor for human health.

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
Phosphoric acid	7664-38-2	Green algae	Experimental	72 hours	EC50	>100 mg/l
Phosphoric acid	7664-38-2	Water flea	Experimental	48 hours	EC50	>100 mg/l
Phosphoric acid	7664-38-2	Green algae	Experimental	72 hours	NOEC	100 mg/l
Silica	112945-52-5	Green Algae	Experimental	72 hours	EC50	>100 mg/l
Silica	112945-52-5	Water flea	Experimental	24 hours	EC50	>100 mg/l
Silica	112945-52-5	Zebra Fish	Experimental	96 hours	LC50	>100 mg/l
Silica	112945-52-5	Green Algae	Experimental	72 hours	NOEC	60 mg/l
Polyglycol	25322-68-3	Activated sludge	Experimental		EC50	>1,000 mg/l
Polyglycol	25322-68-3	Atlantic Salmon	Experimental	96 hours	LC50	>1,000 mg/l
Aluminum oxide	1344-28-1	Fish	Experimental	96 hours	LC50	>100 mg/l
Aluminum oxide	1344-28-1	Green Algae	Experimental	72 hours	EC50	>100 mg/l
Aluminum oxide	1344-28-1	Water flea	Experimental	48 hours	LC50	>100 mg/l
Aluminum oxide	1344-28-1	Green Algae	Experimental	72 hours	NOEC	>100 mg/l

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Phosphoric acid	7664-38-2	Data not availbl-insufficient			N/A	
Silica	112945-52-5	Data not availbl-insufficient			N/A	
Polyglycol	25322-68-3	Experimental Biodegradation	28 days	BOD	53 % BOD/ThBOD	OECD 301C - MITI test (I)

Aluminum oxide	1344-28-1	Data not availbl-insufficient			N/A	

12.3 : Bioaccumulative potential

Material	Cas No.	Test type	Duration	Study Type	Test result	Protocol
Phosphoric acid	7664-38-2	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Silica	112945-52-5	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Polyglycol	25322-68-3	Estimated Bioconcentration		Bioaccumulation factor	2.3	Estimated: Bioconcentration factor
Aluminum oxide	1344-28-1	Data not available or insufficient for classification	N/A	N/A	N/A	N/A

12.4. Mobility in soil
No test data available.

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. Endocrine disrupting properties

This material does not contain any substances that are assessed to be an endocrine disruptor for environmental effects

12.7. 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

	Ground Transport (ADR)	Air Transport (IATA)	Marine Transport (IMDG)
14.1 UN number	UN1805	UN1805	UN1805
14.2 UN proper shipping name	PHOSPHORIC ACID SOLUTION	PHOSPHORIC ACID SOLUTION	PHOSPHORIC ACID SOLUTION
14.3 Transport hazard class(es)	8	8	8

14.4 Packing group	III	III	III
14.5 Environmental hazards	Not Environmentally Hazardous	Not applicable	Not a Marine Pollutant
14.6 Special precautions for user	Please refer to the other sections of the SDS for further information.	Please refer to the other sections of the SDS for further information.	Please refer to the other sections of the SDS for further information.
14.7 Transport in bulk according to Annex II of Marpol 73/78 and IBC Code	No data available.	No data available.	No data available.
Control Temperature	No data available.	No data available.	No data available.
Emergency Temperature	No data available.	No data available.	No data available.
ADR Tunnel Code	(E)	Not applicable.	Not applicable.
ADR Classification Code	C1	Not applicable.	Not applicable.
ADR Transport Category	4	Not applicable.	Not applicable.
ADR Multiplier	0	0	0
IMDG Segregation Code	Not applicable.	Not applicable.	NONE

Please contact the address or phone number listed on the first page of the SDS for additional information on the transport/shipment of the material by rail (RID) or inland waterways (ADN).

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

H290	May be corrosive to metals.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.

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

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