



## Safety Information Sheet for Medical Devices

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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

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

Carbon monoxide  
Carbon dioxide.

#### Condition

During combustion.  
During combustion.

### 5.3. Advice for fire-fighters

Wear full protective clothing, including helmet, self-contained, positive pressure or pressure demand breathing apparatus, bunker coat and pants, bands around arms, waist and legs, face mask, and protective covering for exposed areas of the head.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

Evacuate area. Ventilate the area with fresh air. For large spill, or spills in confined spaces, provide mechanical ventilation to disperse or exhaust vapours, in accordance with good industrial hygiene practice. Refer to other sections of this SIS for information regarding physical and health hazards, respiratory protection, ventilation, and personal protective equipment.

### 6.2. Environmental precautions

Avoid release to the environment.

### 6.3. Methods and material for containment and cleaning up

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/m <sup>3</sup> ;TWA(as inhalable	

Aluminum oxide	1344-28-1	UK HSC	dust):6 mg/m3 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  
CELL: 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	<i>Not applicable.</i>
Boiling point/boiling range	<i>No data available.</i>
Flammability (solid, gas)	Not applicable.
Flammable Limits(LEL)	<i>No data available.</i>
Flammable Limits(UEL)	<i>No data available.</i>
Flash point	> 100 °C [Test Method:Closed Cup]
Autoignition temperature	<i>No data available.</i>
Relative density	1.1 - 1.2 [Ref Std:WATER=1]
pH	< 1
Kinematic Viscosity	<i>No data available.</i>
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	<i>No data available.</i>
Evaporation rate	<i>No data available.</i>
Molecular weight	<i>No data available.</i>
Percent volatile	<i>No data available.</i>

## 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

<u>Substance</u>	<u>Condition</u>
None known.	

Refer to section 5.2 for hazardous decomposition products during combustion.

## SECTION 11: Toxicological information

The information below may not agree with the EU material classification in Section 2 and/or the ingredient classifications in Section 3 if specific ingredient classifications are mandated by a competent authority. In addition, statements and data presented in Section 11 are based on UN GHS calculation rules and classifications derived from 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 available or insufficient			N/A	
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### 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

<b>14.4 Packing group</b>	III	III	III
<b>14.5 Environmental hazards</b>	Not Environmentally Hazardous	Not applicable	Not a Marine Pollutant
<b>14.6 Special precautions for user</b>	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.
<b>14.7 Transport in bulk according to Annex II of Marpol 73/78 and IBC Code</b>	No data available.	No data available.	No data available.
<b>Control Temperature</b>	No data available.	No data available.	No data available.
<b>Emergency Temperature</b>	No data available.	No data available.	No data available.
<b>ADR Tunnel Code</b>	(E)	Not applicable.	Not applicable.
<b>ADR Classification Code</b>	C1	Not applicable.	Not applicable.
<b>ADR Transport Category</b>	4	Not applicable.	Not applicable.
<b>ADR Multiplier</b>	0	0	0
<b>IMDG Segregation Code</b>	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](http://www.3M.com/uk)**