

Safety Information Sheet for Medical Devices

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 29-8286-6
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 2.00

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 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

3MTM ScotchbondTM 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.

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12/08/2021

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

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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	$(C \ge 25\%)$ Skin Corr. 1B, H314
	(EC-No.) 231-633-2	(10% =< C < 25%) Skin Irrit. 2, H315
		$(C \ge 25\%)$ 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.

Eve 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.

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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

SubstanceConditionCarbon monoxideDuring 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

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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 stateLiquid.Specific Physical Form:GelColourBlue

Odor Slight Odor, Characteristic Odour

Melting point/freezing pointNot applicable.Boiling point/boiling rangeNo data available.Flammability (solid, gas)Not applicable.Flammable Limits(LEL)No data available.Flammable Limits(UEL)No data available.

Flash point > 100 °C [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

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9.2. Other information

9.2.2 Other safety characteristics

EU Volatile Organic CompoundsNo data available.Evaporation rateNo data available.Molecular weightNo data available.Percent volatileNo 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

None known.

Condition

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,

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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

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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

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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.

CAS#	Organism	Type	Exposure	Test endpoint	Test result
7664-38-2	Green algae	Experimental	72 hours	EC50	>100 mg/l
7664-38-2	Water flea	Experimental	48 hours	EC50	>100 mg/l
7664-38-2	Green algae	Experimental	72 hours	NOEC	100 mg/l
112945-52-5	Green Algae	Experimental	72 hours	EC50	>100 mg/l
112945-52-5	Water flea	Experimental	24 hours	EC50	>100 mg/l
112945-52-5	Zebra Fish	Experimental	96 hours	LC50	>100 mg/l
112945-52-5	Green Algae	Experimental	72 hours	NOEC	60 mg/l
25322-68-3	Activated sludge	Experimental		EC50	>1,000 mg/l
25322-68-3	Atlantic Salmon	Experimental	96 hours	LC50	>1,000 mg/l
1344-28-1	Fish	Experimental	96 hours	LC50	>100 mg/l
1344-28-1	Green Algae	Experimental	72 hours	EC50	>100 mg/l
1344-28-1	Water flea	Experimental	48 hours	LC50	>100 mg/l
1344-28-1	Green Algae	Experimental	72 hours	NOEC	>100 mg/l
	7664-38-2 7664-38-2 7664-38-2 112945-52-5 112945-52-5 112945-52-5 25322-68-3 25322-68-3 1344-28-1 1344-28-1	7664-38-2 Green algae 7664-38-2 Water flea 7664-38-2 Green algae 112945-52-5 Green Algae 112945-52-5 Water flea 112945-52-5 Green Algae 25322-68-3 Activated sludge 25322-68-3 Atlantic Salmon 1344-28-1 Fish 1344-28-1 Green Algae 1344-28-1 Water flea	7664-38-2 Green algae Experimental 7664-38-2 Water flea Experimental 7664-38-2 Green algae Experimental 112945-52-5 Green Algae Experimental 112945-52-5 Water flea Experimental 112945-52-5 Green Algae Experimental 112945-52-5 Green Algae Experimental 112945-52-5 Green Algae Experimental 25322-68-3 Activated sludge Experimental 25322-68-3 Atlantic Salmon Experimental 1344-28-1 Fish Experimental 1344-28-1 Green Algae Experimental 1344-28-1 Green Algae Experimental	7664-38-2 Green algae Experimental 72 hours 7664-38-2 Water flea Experimental 48 hours 7664-38-2 Green algae Experimental 72 hours 112945-52-5 Green Algae Experimental 24 hours 112945-52-5 Water flea Experimental 96 hours 112945-52-5 Green Algae Experimental 72 hours 25322-68-3 Activated sludge Experimental 96 hours 1344-28-1 Fish Experimental 96 hours 1344-28-1 Green Algae Experimental 72 hours 1344-28-1 Green Algae Experimental 48 hours	7664-38-2 Green algae Experimental 72 hours EC50 7664-38-2 Water flea Experimental 48 hours EC50 7664-38-2 Green algae Experimental 72 hours NOEC 112945-52-5 Green Algae Experimental 24 hours EC50 112945-52-5 Water flea Experimental 96 hours LC50 112945-52-5 Green Algae Experimental 72 hours NOEC 25322-68-3 Activated sludge Experimental EC50 25322-68-3 Atlantic Salmon Experimental 96 hours LC50 1344-28-1 Fish Experimental 96 hours LC50 1344-28-1 Green Algae Experimental 72 hours EC50 1344-28-1 Water flea Experimental 48 hours LC50

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)

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

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

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14.4 Packing group	III	III	III	
14.5 Environmental hazards	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		Not a Marine Pollutant	
	precautions Please refer to the other sections of the SDS for further information. Please refer to of the SDS for information.		sections of the SDS for further information.	
14.7 Transport in bulk according to Annex II of Marpol 73/78 and IBC Code	According to Annex II of Marpol 73/78 and IBC		No data available.	
Control Temperature	ontrol Temperature No data available.		No data available.	
Emergency Temperature	Emergency Temperature 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	ADR Transport Category 4		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.

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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

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Safety Data Sheet

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 02/09/2016

Transportation version number: 1.00 (26/07/2011)

This Safety Data Sheet has been prepared in accordance with the REACH Regulation (EC) 1907/2006 and its modifications.

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

3M ESPE ADPER SCOTCHBOND 1 XT

Product Identification Numbers

70-2010-3675-6

7000054284

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

Identified uses

Dental Product

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

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.

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CLASSIFICATION:

Flammable Liquid, Category 2 - Flam. Liq. 2; H225 Serious Eye Damage/Eye Irritation, Category 2 - Eye Irrit. 2; H319

Skin Corrosion/Irritation, Category 2 - Skin Irrit. 2; H315 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

DANGER.

Symbols:

GHS02 (Flame) |GHS07 (Exclamation mark) |

Pictograms





Ingredients:

Ingredient	CAS Nbr	% by Wt
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)]	1565-94-2	10 - 20
bismethacrylate		
2-Hydroxyethyl methacrylate	868-77-9	5 - 15
2-Hydroxy-1,3-propanediyl bismethacrylate	1830-78-0	5 - 10
7,7,9(or 7,9,9)-Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-	72869-86-4	1 - 5
diyl bismethacrylate		

HAZARD STATEMENTS:

H225 Highly flammable liquid and vapour.
H319 Causes serious eye irritation.
H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

PRECAUTIONARY STATEMENTS

Prevention:

P210A Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P280E Wear protective gloves.

Response:

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

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

P370 + P378G In case of fire: Use a fire fighting agent suitable for flammable liquids such as dry chemical or

carbon dioxide to extinguish.

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.	REACH Registration	% by \	Wt	Classification
			No.			
Ethanol	64-17-5	200-578-6		25 -	35	Flam. Liq. 2, H225 Eye Irrit. 2, H319
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	1565-94-2	216-367-7		10 -	20	Skin Sens. 1B, H317
Amorphous silica (7631-86-9) surface modified with organofunctional silane and methacryloxypropyltrimethoxysilane (2530-85-0)	None			10 -	20	Substance not classified as hazardous
2-Hydroxyethyl methacrylate	868-77-9	212-782-2	01- 2119490169- 29	5 -	15	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317 - Nota D
2-Hydroxy-1,3-propanediyl bismethacrylate	1830-78-0	217-388-4		5 -	10	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335
2-Propenoic acid, polymer with methylenebutanedioic acid	25948-33-8			5 -	10	Substance not classified as hazardous
Non-Hazardous Ingredients	Mixture			< 5		Substance not classified as hazardous
7,7,9(or 7,9,9)-Trimethyl-4,13-dioxo- 3,14-dioxa-5,12-diazahexadecane-1,16- diyl bismethacrylate	72869-86-4	276-957-5		1 -	5	Skin Sens. 1B, H317
Diphenyliodonium hexafluorophosphate	58109-40-3	<u> </u>		< 1		Acute Tox. 2, H300
Ethyl 4-dimethylaminobenzoate	10287-53-3	233-634-3		< 1		Substance not classified as hazardous

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

For information on ingredient occupational exposure limits or PBT or vPvB status, see sections 8 and 12 of this SDS

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.

4.2. Most important symptoms and effects, both acute and delayed

See Section 11.1 Information on toxicological effects

4.3. Indication of any immediate medical attention and special treatment required

Not applicable

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

In case of fire: Use a fire fighting agent suitable for flammable liquids such as dry chemical or carbon dioxide to extinguish.

5.2. Special hazards arising from the substance or mixture

Closed containers exposed to heat from fire may build pressure and explode.

Hazardous Decomposition or By-Products

Substance
Carbon monoxide.
Carbon dioxide.

Condition

During combustion. During combustion.

5.3. Advice for fire-fighters

Water may not effectively extinguish fire; however, it should be used to keep fire-exposed containers and surfaces cool and prevent explosive rupture.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Evacuate area. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Use only non-sparking tools. 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. Warning! A motor could be an ignition source and could cause flammable gases or vapours in the spill area to burn or explode. Refer to other sections of this SDS 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 using non-sparking tools. Place in a metal container approved for transportation by appropriate authorities. Clean up residue with an appropriate solvent selected by a qualified and authorised person. Ventilate the area with fresh air. Read and follow safety precautions on the solvent label and Safety Data Sheet. Seal the container. Dispose of collected material as soon as possible.

6.4. Reference to other sections

Refer to Section 8 and Section 13 for more information

SECTION 7: Handling and storage

7.1. Precautions for safe handling

A no-touch technique is recommended. If skin contact occurs, wash skin with soap and water. Acrylates may penetrate commonly-used gloves. If product contacts glove, remove and discard glove, wash hands immediately with soap and water and then re-glove. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Avoid breathing dust/fume/gas/mist/vapours/spray. Do not get in eyes, on skin, or on clothing. Do not eat, drink or smoke when using this product. Wash thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Avoid release to the environment. Wash contaminated clothing before reuse. Avoid contact with oxidising agents (eg. chlorine, chromic acid etc.)

7.2. Conditions for safe storage including any incompatibilities

Store in a well-ventilated place. Keep cool. Keep container tightly closed. Store away from heat. Store away from acids. Store away from oxidising agents.

7.3. Specific end use(s)

See information in Section 7.1 and 7.2 for handling and storage recommendations. See Section 8 for exposure controls and personal protection recommendations.

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

Ethanol 64-17-5 UK HSC TWA:1920 mg/m³(1000 ppm)

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 data sheet.

Derived no effect level (DNEL)

Ingredient	Degradation	Population	Human exposure	DNEL
	Product		pattern	
2-Hydroxyethyl		Worker	Dermal, Long-term	1.3 mg/kg bw/d
methacrylate			exposure (8 hours),	
•			Systemic effects	
2-Hydroxyethyl		Worker	Inhalation, Long-term	4.9 mg/m ³
methacrylate			exposure (8 hours),	
•			Systemic effects	

Predicted no effect concentrations (PNEC)

Ingredient	Degradation Product	Compartment	PNEC
2-Hydroxyethyl methacrylate		Agricultural soil	0.476 mg/kg d.w.
2-Hydroxyethyl methacrylate		Freshwater	0.482 mg/l
2-Hydroxyethyl methacrylate		Freshwater sediments	3.79 mg/kg d.w.
2-Hydroxyethyl methacrylate		Intermittent releases to water	1 mg/l
2-Hydroxyethyl methacrylate		Marine water	0.482 mg/l
2-Hydroxyethyl methacrylate		Marine water sediments	3.79 mg/kg d.w.
2-Hydroxyethyl methacrylate		Sewage Treatment Plant	10 mg/l

8.2. Exposure controls

In addition, refer to the annex for more information.

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.

Skin/hand protection

See Section 7.1 for additional information on skin protection.

Respiratory protection

None required.

8.2.3. Environmental exposure controls

Refer to Annex

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state Liquid.
Specific Physical Form: Liquid.

Appearance/Odour Slight acrylate odour, white to clear

Odour threshold No data available. PH No data available.

Boiling point/boiling range 78 °C

Melting pointNot applicable.Flammability (solid, gas)Not applicable.Explosive propertiesNot classifiedOxidising propertiesNot classified

Flash point 18.5 °C [Test Method:Closed Cup]

Autoignition temperature 410 °C

Flammable Limits(LEL)

Flammable Limits(UEL)

No data available.

No data available.

No data available.

No data available.

Relative density 1.075 [*Ref Std:* WATER=1]

Water solubility Negligible Solubility- non-water No data available.

Partition coefficient: n-octanol/water

Evaporation rate

Vapour density

Decomposition temperature

No data available.

9.2. Other information

Molecular weightNo data available.Percent volatileNo 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

Heat.

Sparks and/or flames.

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

Exposures needed to cause the following health effect(s) are not expected during normal, intended use:

Respiratory tract irritation: Signs/symptoms may include cough, sneezing, nasal discharge, headache, hoarseness, and nose and throat pain.

May cause additional health effects (see below).

Skin contact

May be harmful in contact with skin. 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

May be harmful if swallowed.

Gastrointestinal irritation: Signs/symptoms may include abdominal pain, stomach upset, nausea, vomiting and diarrhoea. May cause additional health effects (see below).

Additional Health Effects:

Single exposure may cause target organ effects:

Exposures needed to cause the following health effect(s) are not expected during normal, intended use:

Central nervous system (CNS) depression: Signs/symptoms may include headache, dizziness, drowsiness, incoordination, nausea, slowed reaction time, slurred speech, giddiness, and unconsciousness.

Additional information:

This product contains ethanol. Alcoholic beverages and ethanol in alcoholic beverages have been classified by the International Agency for Research on Cancer as carcinogenic to humans. There are also data associating human consumption of alcoholic beverages with developmental toxicity and liver toxicity. Exposure to ethanol during the foreseeable use of this product is not expected to cause cancer, developmental toxicity, or liver toxicity.

Toxicological Data

If a component is disclosed in section 3 but does not appear in a table below, either no data are available for that endpoint or the data are not sufficient for classification.

Acute Toxicity

Name	Route	Species	Value
Overall product	Ingestion		No data available; calculated ATE2,000 - 5,000 mg/kg
Overall product	Dermal	Rabbit	LD50 > 2,000 mg/kg
Ethanol	Dermal	Rabbit	LD50 > 15,800 mg/kg
Ethanol	Inhalation- Vapour (4 hours)	Rat	LC50 124.7 mg/l
Ethanol	Ingestion	Rat	LD50 17,800 mg/kg
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	Ingestion		LD50 estimated to be 2,000 - 5,000 mg/kg
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	Dermal	Professio nal judgeme nt	LD50 estimated to be 2,000 - 5,000 mg/kg
Amorphous silica (7631-86-9) surface modified with organofunctional silane and methacryloxypropyltrimethoxysilane (2530-85-0)	Dermal	Rabbit	LD50 > 5,000 mg/kg
Amorphous silica (7631-86-9) surface modified with organofunctional silane and methacryloxypropyltrimethoxysilane (2530-85-0)	Inhalation- Dust/Mist (4 hours)	Rat	LC50 > 0.691 mg/l
Amorphous silica (7631-86-9) surface modified with organofunctional silane and methacryloxypropyltrimethoxysilane (2530-85-0)	Ingestion	Rat	LD50 > 5,110 mg/kg
2-Hydroxyethyl methacrylate	Dermal	Rabbit	LD50 > 5,000 mg/kg
2-Hydroxyethyl methacrylate	Ingestion	Rat	LD50 5,564 mg/kg
2-Hydroxy-1,3-propanediyl bismethacrylate	Ingestion	similar compoun ds	LD50 300-2000 mg/kg
2-Propenoic acid, polymer with methylenebutanedioic acid	Ingestion	Rat	LD50 > 5,000 mg/kg
2-Propenoic acid, polymer with methylenebutanedioic acid	Dermal	similar health hazards	LD50 estimated to be > 5,000 mg/kg
7,7,9(or 7,9,9)-Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	Dermal	Professio nal judgeme nt	LD50 estimated to be > 5,000 mg/kg
7,7,9(or 7,9,9)-Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	Ingestion	Rat	LD50 > 5,000 mg/kg
Diphenyliodonium hexafluorophosphate	Ingestion	Rat	LD50 32 mg/kg
Ethyl 4-dimethylaminobenzoate	Dermal	Rat	LD50 > 2,000 mg/kg

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Ethyl 4-dimethylaminobenzoate	Ingestion	Rat	LD50 > 2,000 mg/kg
A men			

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Ethanol	Rabbit	No significant irritation
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)]	Not	Minimal irritation
bismethacrylate	available	
Amorphous silica (7631-86-9) surface modified with organofunctional silane and	Rabbit	No significant irritation
methacryloxypropyltrimethoxysilane (2530-85-0)		
2-Hydroxyethyl methacrylate	Rabbit	Minimal irritation
Diphenyliodonium hexafluorophosphate	Rabbit	No significant irritation
Ethyl 4-dimethylaminobenzoate	Rabbit	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
Ethanol	Rabbit	Severe irritant
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)]	Not	Moderate irritant
bismethacrylate	available	
Amorphous silica (7631-86-9) surface modified with organofunctional silane and	Rabbit	No significant irritation
methacryloxypropyltrimethoxysilane (2530-85-0)		
2-Hydroxyethyl methacrylate	Rabbit	Moderate irritant
Diphenyliodonium hexafluorophosphate	Rabbit	Mild irritant
Ethyl 4-dimethylaminobenzoate	Rabbit	Mild irritant

Skin Sensitisation

Name	Species	Value
Ethanol	Human	Not classified
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)]	Guinea	Sensitising
bismethacrylate	pig	
Amorphous silica (7631-86-9) surface modified with organofunctional silane and	Human	Not classified
methacryloxypropyltrimethoxysilane (2530-85-0)	and	
	animal	
2-Hydroxyethyl methacrylate	Human	Sensitising
	and	
	animal	
7,7,9(or 7,9,9)-Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl	Guinea	Sensitising
bismethacrylate	pig	

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
Ethanol	In Vitro	Some positive data exist, but the data are not sufficient for classification
Ethanol	In vivo	Some positive data exist, but the data are not sufficient for classification
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	In Vitro	Some positive data exist, but the data are not sufficient for classification
Amorphous silica (7631-86-9) surface modified with organofunctional silane and methacryloxypropyltrimethoxysilane (2530-85-0)	In Vitro	Not mutagenic
2-Hydroxyethyl methacrylate	In vivo	Not mutagenic
2-Hydroxyethyl methacrylate	In Vitro	Some positive data exist, but the data are not sufficient for classification
Diphenyliodonium hexafluorophosphate	In Vitro	Some positive data exist, but the data are not sufficient for classification

Carcinogenicity

Name	Route	Species	Value
Ethanol	Ingestion	Multiple animal species	Some positive data exist, but the data are not sufficient for classification
Amorphous silica (7631-86-9) surface modified with organofunctional silane and methacryloxypropyltrimethoxysilane (2530-85-0)	Not specified.	Mouse	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
Ethanol	Inhalation	Not classified for development	Rat	NOAEL 38 mg/l	during gestation
Ethanol	Ingestion	Not classified for development	Rat	NOAEL 5,200 mg/kg/day	premating & during gestation
(1-methylethylidene)bis[4,1- phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	Ingestion	Not classified for female reproduction	Mouse	NOAEL 0.8 mg/kg/day	premating & during gestation
(1-methylethylidene)bis[4,1- phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	Ingestion	Not classified for male reproduction	Mouse	NOAEL 0.8 mg/kg/day	premating & during gestation
(1-methylethylidene)bis[4,1- phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	Ingestion	Not classified for development	Mouse	NOAEL 0.8 mg/kg/day	premating & during gestation
Amorphous silica (7631-86-9) surface modified with organofunctional silane and methacryloxypropyltrimethoxysilane (2530-85-0)	Ingestion	Not classified for female reproduction	Rat	NOAEL 509 mg/kg/day	1 generation
Amorphous silica (7631-86-9) surface modified with organofunctional silane and methacryloxypropyltrimethoxysilane (2530-85-0)	Ingestion	Not classified for male reproduction	Rat	NOAEL 497 mg/kg/day	1 generation
Amorphous silica (7631-86-9) surface modified with organofunctional silane and methacryloxypropyltrimethoxysilane (2530-85-0)	Ingestion	Not classified for development	Rat	NOAEL 1,350 mg/kg/day	during organogenesis
2-Hydroxyethyl methacrylate	Ingestion	Not classified for female reproduction	Rat	NOAEL 1,000 mg/kg/day	premating & during gestation
2-Hydroxyethyl methacrylate	Ingestion	Not classified for male reproduction	Rat	NOAEL 1,000 mg/kg/day	49 days
2-Hydroxyethyl methacrylate	Ingestion	Not classified for development	Rat	NOAEL 1,000 mg/kg/day	premating & during gestation

Target Organ(s)

Specific Target Organ Toxicity - single exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Ethanol	Inhalation	central nervous system depression	May cause drowsiness or dizziness	Human	LOAEL 2.6 mg/l	30 minutes
Ethanol	Inhalation	respiratory irritation	Some positive data exist, but the data are not sufficient for classification	Human	LOAEL 9.4 mg/l	not available
Ethanol	Ingestion	central nervous system depression	May cause drowsiness or dizziness	Multiple animal species	NOAEL not available	
Ethanol	Ingestion	kidney and/or bladder	Not classified	Dog	NOAEL 3,000 mg/kg	
2-Propenoic acid, polymer with methylenebutanedioic	Ingestion	nervous system	Not classified	Rat	NOAEL 5,000 mg/kg	

acid						
Diphenyliodonium	Inhalation	respiratory irritation	Not classified	Not	Irritation	
hexafluorophosphate				available	Equivocal	

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Ethanol	Inhalation	liver	Some positive data exist, but the data are not sufficient for classification	Rabbit	LOAEL 124 mg/l	365 days
Ethanol	Inhalation	hematopoietic system immune system	Not classified	Rat	NOAEL 25 mg/l	14 days
Ethanol	Ingestion	liver	Some positive data exist, but the data are not sufficient for classification	Rat	LOAEL 8,000 mg/kg/day	4 months
Ethanol	Ingestion	kidney and/or bladder	Not classified	Dog	NOAEL 3,000 mg/kg/day	7 days
(1- methylethylidene)bis[4,1- phenyleneoxy(2-hydroxy- 3,1-propanediyl)] bismethacrylate	Ingestion	endocrine system liver nervous system kidney and/or bladder	Not classified	Mouse	NOAEL 0.8 mg/kg/day	premating & during gestation
Amorphous silica (7631- 86-9) surface modified with organofunctional silane and methacryloxypropyltrimet hoxysilane (2530-85-0)	Inhalation	respiratory system silicosis	Not classified	Human	NOAEL Not available	occupational exposure
2-Propenoic acid, polymer with methylenebutanedioic acid	Ingestion	endocrine system hematopoietic system liver	Not classified	Rat	NOAEL 200 mg/kg/day	28 days
2-Propenoic acid, polymer with methylenebutanedioic acid	Ingestion	heart bone, teeth, nails, and/or hair immune system muscles nervous system eyes kidney and/or bladder respiratory system vascular system	Not classified	Rat	NOAEL 2,000 mg/kg/day	28 days

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 SDS for additional toxicological information on this material and/or its components.

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 Nbr	Organism	Type	Exposure	Test endpoint	Test result
2-Hydroxy-1,3-	1830-78-0	Guppy	Experimental	96 hours	LC50	43.2 mg/l

propanediyl		T		Ī		
bismethacrylate						
Diphenyliodoni		Water flea	Experimental	48 hours	EC50	9.5 mg/l
um	00103 10 2	1, 4, 4, 4, 4, 4, 4, 4, 4, 4, 4, 4, 4, 4,	Z.i.p • i i i i i i i i i i i i i i i i i i			
hexafluorophos						
phate						
Ethanol	64-17-5	Water flea	Experimental	48 hours	EC50	9,300 mg/l
Ethanol	64-17-5	Green algae	Experimental	96 hours	EC50	1,000 mg/l
Ethanol	64-17-5	Rainbow trout	Experimental	96 hours	LC50	42 mg/l
2-	868-77-9	Water flea	Experimental	48 hours	EC50	380 mg/l
Hydroxyethyl		Water fied	Experimental	40 Hours	Leso	Joo mg/1
methacrylate						
2-	868-77-9	Fathead	Experimental	96 hours	LC50	227 mg/l
Hydroxyethyl		minnow	Experimental) Hours	Leso	22 / 111g/1
methacrylate		IIIIIIIIO W				
Ethyl 4-	10287-53-3	Fathead	Estimated	96 hours	LC50	8.8 mg/l
dimethylamino	10207 33 3	minnow	Estimated) Hours	Leso	0.0 mg/1
benzoate		iiiiiiio w				
2-	868-77-9	Green Algae	Experimental	72 hours	EC50	345 mg/l
Hydroxyethyl		Green Aigac	Daperinicitai	, 2 110013		J-7 1115/1
methacrylate						
Ethanol	64-17-5	Water flea	Experimental	11 days	NOEC	9.6 mg/l
2-	868-77-9	Water flea	Experimental	21 days	NOEC	24.1 mg/l
Hydroxyethyl	000-77-9	w ater riea	Experimental	21 days	NOLC	24.1 mg/1
methacrylate						
2-	868-77-9	Green Algae	Experimental	72 hours	NOEC	160 mg/l
Hydroxyethyl	000-77-9	Green Aigae	Experimental	/2 nours	NOEC	100 mg/1
methacrylate						
7,7,9(or 7,9,9)-	72869-86-4	1	Data not			
7,7,9(01 7,9,9)- Trimethyl-	/2809-80-4		available or			
4,13-dioxo-			insufficient for			
3,14-dioxa-			classification			
5,12-			Classification			
diazahexadecan						
e-1,16-diyl						
bismethacrylate						
2-Propenoic	25948-33-8		Data not			
acid, polymer	23740-33-0		available or			
with			insufficient for			
methylenebuta			classification			
nedioic acid			Classification			
Amorphous	None	†	Data not	1	1	
silica (7631-86-	1 10110		available or			
9) surface			insufficient for			
modified with			classification			
organofunction		1		1		
al silane and		1		1		
methacryloxypr						
opyltrimethoxy						
silane (2530-						
85-0)		1		1		
(1-	1565-94-2		Data not			
methylethylide			available or			
ne)bis[4,1-			insufficient for			
phenyleneoxy(classification			
<u> </u>		-		<u> </u>		<u> </u>

2-hydroxy-3,1-			
propanediyl)]			
bismethacrylate			

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Non-Hazardous Ingredients	Mixture	Data not available or	N/A	N/A	N/A	N/A
ingredients		insufficient for				
		classification				
Ethyl 4-	10287-53-3	Estimated	28 days	BOD	29 % weight	OECD 301C - MITI
dimethylamino		Biodegradation	-			test (I)
benzoate						
(1-	1565-94-2	Estimated	28 days	BOD	33 % weight	OECD 301C - MITI
methylethylide		Biodegradation				test (I)
ne)bis[4,1- phenyleneoxy(
2-hydroxy-3,1-						
propanediyl)]						
bismethacrylate						
2-Hydroxy-1,3-		Experimental	28 days	BOD	84 % weight	OECD 301F -
propanediyl		Biodegradation				Manometric
bismethacrylate						respirometry
2-Propenoic	25948-33-8	Data not	N/A	N/A	N/A	N/A
acid, polymer		available or				
with methylenebuta		insufficient for classification				
nedioic acid		Classification				
Diphenyliodoni	58109-40-3	Data not	N/A	N/A	N/A	N/A
um		available or				
hexafluorophos		insufficient for				
phate		classification				
Ethanol	64-17-5	Experimental Biodegradation	14 days	BOD	89 % weight	OECD 301C - MITI test (I)
7,7,9(or 7,9,9)-	72869-86-4	Estimated	28 days	BOD	52 % weight	OECD 301C - MITI
Trimethyl-		Biodegradation				test (I)
4,13-dioxo- 3,14-dioxa-						
5,12-						
diazahexadecan						
e-1,16-diyl						
bismethacrylate						
2-	868-77-9	Experimental		Hydrolytic	10.9 days (t	Other methods
Hydroxyethyl		Hydrolysis		half-life	1/2)	
methacrylate	0.60.77.0	D	1.4.1	DOD	05.0/	OF CD 201C ACT
2-	868-77-9	Experimental	14 days	BOD	95 % weight	OECD 301C - MITI
Hydroxyethyl methacrylate		Biodegradation				test (I)
Amorphous	None	Data not	N/A	N/A	N/A	N/A
silica (7631-86-		available or	11 1/ 1 1	1 1/2 1	11/11	1 1/ 1 1
9) surface		insufficient for				
modified with		classification				
organofunction						
al silane and						

3M	ESPE	ADPER	SCOTCHBOND	1 XT

methacryloxypr			
opyltrimethoxy			
silane (2530-			
85-0)			

12.3 : Bioaccumulative potential

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Non-Hazardous Ingredients		Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Ethyl 4- dimethylamino benzoate	10287-53-3	Estimated Bioconcentrati on		Bioaccumulatio n factor	19	Estimated: Bioconcentration factor
(1- methylethylide ne)bis[4,1- phenyleneoxy(2-hydroxy-3,1- propanediyl)] bismethacrylate	1565-94-2	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
2-Hydroxy-1,3- propanediyl bismethacrylate		Data not available or insufficient for classification	N/A	N/A	N/A	N/A
2-Propenoic acid, polymer with methylenebuta nedioic acid	25948-33-8	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Diphenyliodoni um hexafluorophos phate	58109-40-3	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Ethanol	64-17-5	Experimental Bioconcentrati on		Log Kow	-0.31	Other methods
7,7,9(or 7,9,9)- Trimethyl- 4,13-dioxo- 3,14-dioxa- 5,12- diazahexadecan e-1,16-diyl bismethacrylate		Estimated Bioconcentrati on		Bioaccumulatio n factor	5	Estimated: Bioconcentration factor
2- Hydroxyethyl methacrylate	868-77-9	Experimental Bioconcentrati on		Log Kow	0.47	Other methods
Amorphous silica (7631-86- 9) surface modified with organofunction al silane and	None	Data not available or insufficient for classification	N/A	N/A	N/A	N/A

methacryloxypr

methacryloxypr		
opyltrimethoxy		
silane (2530-		
85-0)		

12.4. Mobility in soil

Please contact manufacturer for more details

12.5. Results of the PBT and vPvB assessment

No information available at this time, contact manufacturer for more details

12.6. Other adverse effects

Material	CAS Nbr	Ozone Depletion Potential	Global Warming Potential
ethyl alcohol	64-17-5	0	
Non-Hazardous Ingredients	Mixture	0	

SECTION 13: Disposal considerations

13.1 Waste treatment methods

See Section 11.1 Information on toxicological effects

Incinerate in a permitted waste incineration facility.

The coding of a waste stream is based on the application of the product by the consumer. Since this is out of the control of 3M, no waste code(s) for products after use will be provided. Please refer to the European Waste Code (EWC - 2000/532/EC and amendments) to assign the correct waste code to your waste stream. Ensure national and/or regional regulations are complied with and always use a licensed waste contractor.

EU waste code (product as sold)

180106* Chemicals consisting of or containing dangerous substances.

SECTION 14: Transportation information

70-2010-3675-6

ADR/RID: DANGEROUS GOODS IN EXCEPTED QUANTITIES, CLASS 3, II, (--).

IMDG-CODE: UN1133, ADHESIVES, 3, II, IMDG-Code segregation code: NONE, Dangerous Goods in excepted

Quantities, EMS: FE,SD.

ICAO/IATA: DANGEROUS GOODS IN EXCEPTED QUANTITIES OF CLASS 3,UN1133, II.

SECTION 15: Regulatory information

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

Global inventory status

Contact 3M for more information.

15.2. Chemical Safety Assessment

A chemical safety assessment has been carried out for the relevant substances in this material by the registrant in accordance with regulation REGULATION (EC) No 1907/2006

SECTION 16: Other information

List of relevant H statements

H225	Highly flammable liquid and vapour.
H300	Fatal if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

Revision information:

Professional Mixing and Application: Section 16: Annex information was added.

Section 01: SAP Material Numbers information was added.

Section 3: Composition/Information of ingredients table information was added.

Section 3: Composition/Information of ingredients table information was deleted.

Section 8: 8.2. Exposure controls information information was added.

Section 8: 8.2.3. Environmental exposure controls information information was added.

Section 8: DNEL table row information was added.

Section 8: PNEC table row information was added.

Section 11: Acute Toxicity table information was modified.

Section 11: Carcinogenicity Table information was modified.

Section 11: Germ Cell Mutagenicity Table information was modified.

Section 11: Reproductive Toxicity Table information was modified.

Section 11: Serious Eye Damage/Irritation Table information was modified.

Section 11: Skin Corrosion/Irritation Table information was modified.

Section 11: Skin Sensitization Table information was modified.

Section 11: Target Organs - Repeated Table information was modified.

Section 11: Target Organs - Single Table information was modified.

Section 12: Component ecotoxicity information information was modified.

Section 12: Persistence and Degradability information information was modified.

Section 12:Bioccumulative potential information information was modified.

Section 15: Chemical Safety Assessment information was modified.

Annex: Prediction of exposure statement information was added.

Annex

1. Title	
Substance identification	2-Hydroxyethyl methacrylate; EC No. 212-782-2; CAS Nbr 868-77-9;
Exposure Scenario Name	Hand-mixing of preparations, e.g. plasters, resins, two-component adhesives.
Lifecycle Stage	Widespread use by professional workers
Contributing activities	PROC 0 -Other Process or activity
	ERC 08c -Widespread use leading to inclusion into/onto article (indoor)
Processes, tasks and activities covered	Application of substances/mixtures by dentist to patient's mouth on the dental hard
	tissue. Manual application of product.
2. Operational conditions and risk mana	gement measures
Operating Conditions	Physical state:Liquid.
	General operating conditions:
	Duration of use: 8 hours/day;
	Frequency of exposure at workplace [for one worker]: 5 days/week;
	Indoors with good general ventilation;

Risk management measures	Under the operational conditions described above the following risk management measures apply: General risk management measures: Human health: Goggles - Chemical resistant; Protective Gloves - Chemical resistant; Environmental: None needed;
Waste management measures	No use-specific waste management measures are required for this product. Refer to Section 13 of main SDS for disposal instructions:
3. Prediction of exposure	
Prediction of exposure	Human and environmental exposures are not expected to exceed the DNELs and PNECs when the identified risk management measures are adopted.

DISCLAIMER: The information on this Safety Data Sheet is based on our experience and is correct to the best of our knowledge at the date of publication, but we do not accept any liability for any loss, damage or injury resulting from its use (except as required by law). The information may not be valid for any use not referred to in this Data Sheet or use of the product in combination with other materials. For these reasons, it is important that customers carry out their own test to satisfy themselves as to the suitability of the product for their own intended applications.

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