Safety Information Sheet for Medical Devices

Document group:	29-8481-3	**Version number:**	2.00
Revision date:	27/07/2020	**Supersedes date:**	20/07/2020

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

A safety data sheet is not required for this Product. This Safety Information Sheet has been created on a voluntary basis.

IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier
3M™ Scotchbond™ Universal Kit (41255, 41256, 41257, 41292)

Product Identification Numbers
70-2011-3900-6 70-2011-3902-2

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

Identified uses
Medical device; refer to Instructions for Use

Restrictions on Use
For use only by dental professionals.

1.3. Details of the supplier of the safety data sheet

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

1.4. Emergency telephone number
+44 (0)1344 858 000

This product is a kit or a multipart product which consists of multiple, independently packaged components. Safety Information Sheet for Medical Devices for each of these components is included. Please do not separate the component Safety Information Sheet for Medical Devices from this cover page. The document numbers of the Safety Information Sheet for Medical Devices for components of this product are:

29-8286-6, 29-8287-4

TRANSPORTATION INFORMATION

70-2011-3900-6, 70-2011-3902-2

Component 1
ADR/RID: DANGEROUS GOODS IN EXCEPTED QUANTITIES, CLASS 3, III, (--).
IMDG-CODE: UN1133, ADHESIVES, 3, III, IMDG-Code segregation code: NONE, Dangerous Goods in excepted Quantities, EMS: FE,SD.
ICAO/IATA: DANGEROUS GOODS IN EXCEPTED QUANTITIES OF CLASS 3,UN1133, III.

Component 2
ADR/RID: DANGEROUS GOODS IN EXCEPTED QUANTITIES, CLASS 8, III, (--).
IMDG-CODE: UN1805, PHOSPHORIC ACID SOLUTION, 8., III, IMDG-Code segregation code: NONE, Dangerous Goods in excepted Quantities, EMS: FA,SB.
ICAO/IATA: DANGEROUS GOODS IN EXCEPTED QUANTITIES OF CLASS 8,UN1805, III.

KIT LABEL

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

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

Safety Information Sheet for Medical Devices

Document group:	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

Safety Information Sheet for Medical Devices

Document group:	29-8287-4	**Version number:**	2.00
Revision date:	02/05/2022	**Supersedes date:**	23/10/2019

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 (41258)

Product Identification Numbers
LE-F100-1014-6 LE-F100-1014-7 LE-F100-1014-9 70-2011-3903-0

7000055178

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 material has been tested for eye damage/irritation and the test results are reflected in the assigned classification.
This material has been tested for skin corrosion/irritation and the test results do not meet the criteria for classification.

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:
Flammable Liquid, Category 3 - Flam. Liq. 3; H226
Serious Eye Damage/Eye Irritation, Category 1 - Eye Dam. 1; H318
Skin Sensitization, Category 1 - Skin Sens. 1; H317
Reproductive Toxicity, Category 1B - Repr. 1B; H360F
Hazardous to the Aquatic Environment (Chronic), Category 3 - Aquatic Chronic 3; H412

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) |GHS05 (Corrosion) |GHS07 (Exclamation mark) |GHS08 (Health Hazard) |

Pictograms

Ingredients:

Ingredient	CAS Nbr	EC No.	% by Wt
Methacrylate (HEMA)	868-77-9	212-782-2	15 - 25
Phosphorylated methacrylate	1207736-18-2	944-391-4	10 - 20
Aromatic amine	10287-53-3	233-634-3	< 2
Methyacrylated amine	2867-47-2	220-688-8	< 1

HAZARD STATEMENTS:

H226	Flammable liquid and vapour.
H318	Causes serious eye damage.
H317	May cause an allergic skin reaction.
H360F	May damage fertility.
H412	Harmful to aquatic life with long lasting effects.

PRECAUTIONARY STATEMENTS

Prevention:

P201	Obtain special instructions before use.
P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P280B	Wear protective gloves and eye/face protection.

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.
P310	Immediately call a POISON CENTRE or doctor/physician.
P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.

SUPPLEMENTAL INFORMATION:

Supplemental Precautionary Statements:
Restricted to professional users.

2.3. Other hazards

For information on hazards and safe use, please consider the corresponding sections of this document.
This material does not contain any substances that are assessed to be a PBT or vPvB

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]
Dimethacrylate (Bis-GMA)	(CAS-No.) 1565-94-2 (EC-No.) 216-367-7	15 - 25	Substance not classified as hazardous
Methacrylate (HEMA)	(CAS-No.) 868-77-9 (EC-No.) 212-782-2	15 - 25	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317 Nota D
Phosphorylated methacrylate	(CAS-No.) 1207736-18-2 (EC-No.) 944-391-4	10 - 20	Skin Corr. 1B, H314 Eye Dam. 1, H318 Aquatic Acute 1, H400,M=1 Aquatic Chronic 2, H411
Water	(CAS-No.) 7732-18-5 (EC-No.) 231-791-2	10 - 15	Substance not classified as hazardous
Ethyl alcohol	(CAS-No.) 64-17-5 (EC-No.) 200-578-6	10 - 15	Flam. Liq. 2, H225 Eye Irrit. 2, H319
Silane treated silica	(CAS-No.) 122334-95-6 (EC-No.) 310-178-4	7 - 13	Substance not classified as hazardous
Polymeric acid	(CAS-No.) 25948-33-8	1 - 5	Substance not classified as hazardous
BHT	(CAS-No.) 128-37-0 (EC-No.) 204-881-4	< 0.5	Aquatic Chronic 1, H410,M=1 Aquatic Acute 1, H400,M=1
Camphorquinone	(CAS-No.) 10373-78-1 (EC-No.) 233-814-1	< 2	Substance not classified as hazardous
Aromatic amine	(CAS-No.) 10287-53-3 (EC-No.) 233-634-3	< 2	Aquatic Chronic 2, H411 Repr. 1B, H360F
Methyacrylated amine	(CAS-No.) 2867-47-2 (EC-No.) 220-688-8	< 1	Acute Tox. 4, H312 Acute Tox. 4, H302 Skin Sens. 1B, H317 Nota D Skin Corr. 1B, H314 Eye Dam. 1, H318

Any entry in the Identifier(s) column that begins with the numbers 6, 7, 8, or 9 are a Provisional List Number provided by ECHA pending publication of the official EC Inventory Number for the substance.
Please see section 16 for the full text of any H statements referred to in this section

Specific Concentration Limits

Ingredient	Identifier(s)	Specific Concentration Limits
Ethyl alcohol	(CAS-No.) 64-17-5 (EC-No.) 200-578-6	(C >= 50%) 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 wash with soap and water. Remove contaminated clothing and wash before reuse. If signs/symptoms develop, get medical attention.

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 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	Condition
formaldehyde	During combustion.
Carbon monoxide	During combustion.
Carbon dioxide.	During combustion.
Irritant vapours or gases.	During combustion.
Oxides of nitrogen.	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. 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. 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 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. Cover spill area with a fire extinguishing foam that is resistant to polar solvents. 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 using non-sparking tools. Place in a metal container approved for transportation by appropriate authorities. Clean up residue with detergent and water. 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
BHT	128-37-0	UK HSC	TWA:10 mg/m³	
Ethyl alcohol	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 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:	Viscous Liquid
Colour	Yellow
Odor	Characteristic Odour
Melting point/freezing point	*No data available.*
Boiling point/boiling range	>= 78 ºC
Flammability (solid, gas)	Not applicable.
Flammable Limits(LEL)	*No data available.*
Flammable Limits(UEL)	*No data available.*
Flash point	30.5 ºC [*Test Method:*Closed Cup]
Autoignition temperature	*No data available.*
Relative density	1 - 1.2 [*Ref Std:*WATER=1]
pH	
Kinematic Viscosity	*Not applicable.*
Water solubility	Appreciable
Density	1 g/cm3 - 1.2 g/cm3

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.*

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.

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 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
No health effects are expected.

Skin contact
Contact with the skin during product use is not expected to result in significant irritation. Allergic skin reaction (non-photo induced): Signs/symptoms may include redness, swelling, blistering, and itching.

Eye contact
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. May cause additional health effects (see below).

Additional Health Effects:

Reproductive/Developmental Toxicity:
Contains a chemical or chemicals which can cause birth defects or other reproductive harm.

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	Dermal		No data available; calculated ATE >5,000 mg/kg
Overall product	Ingestion		No data available; calculated ATE >5,000 mg/kg
Methacrylate (HEMA)	Dermal	Rabbit	LD50 > 5,000 mg/kg
Methacrylate (HEMA)	Ingestion	Rat	LD50 5,564 mg/kg
Dimethacrylate (Bis-GMA)	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg

Dimethacrylate (Bis-GMA)	Ingestion	Rat	LD50 > 11,700 mg/kg
Ethyl alcohol	Dermal	Rabbit	LD50 > 15,800 mg/kg
Ethyl alcohol	Inhalation-Vapour (4 hours)	Rat	LC50 124.7 mg/l
Ethyl alcohol	Ingestion	Rat	LD50 17,800 mg/kg
Phosphorylated methacrylate	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Phosphorylated methacrylate	Ingestion	Rat	LD50 > 2,000 mg/kg
Silane treated silica	Dermal	Rabbit	LD50 > 5,000 mg/kg
Silane treated silica	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 0.691 mg/l
Silane treated silica	Ingestion	Rat	LD50 > 5,110 mg/kg
Polymeric acid	Ingestion	Rat	LD50 > 5,000 mg/kg
Polymeric acid	Dermal	similar health hazards	LD50 estimated to be > 5,000 mg/kg
Camphorquinone	Dermal	Professional judgement	LD50 estimated to be 2,000 - 5,000 mg/kg
Camphorquinone	Ingestion	Rat	LD50 > 2,000 mg/kg
Aromatic amine	Dermal	Rat	LD50 > 2,000 mg/kg
Aromatic amine	Ingestion	Rat	LD50 > 2,000 mg/kg
Methyacrylated amine	Dermal	Rat	LD50 > 2,000 mg/kg
Methyacrylated amine	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 0.436 mg/l
Methyacrylated amine	Ingestion	Rat	LD50 > 2,000 mg/kg
BHT	Dermal	Rat	LD50 > 2,000 mg/kg
BHT	Ingestion	Rat	LD50 > 2,930 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Overall product	Rabbit	No significant irritation
Methacrylate (HEMA)	Rabbit	Minimal irritation
Dimethacrylate (Bis-GMA)	Rabbit	No significant irritation
Ethyl alcohol	Rabbit	No significant irritation
Phosphorylated methacrylate	In vitro data	Corrosive
Silane treated silica	Rabbit	No significant irritation
Aromatic amine	Rabbit	No significant irritation
Methyacrylated amine	Rabbit	Corrosive
BHT	Human and animal	Minimal irritation

Serious Eye Damage/Irritation

Name	Species	Value
Overall product	In vitro data	Corrosive
Methacrylate (HEMA)	Rabbit	Moderate irritant
Dimethacrylate (Bis-GMA)	In vitro data	No significant irritation
Ethyl alcohol	Rabbit	Severe irritant
Phosphorylated methacrylate	In vitro data	Corrosive
Silane treated silica	Rabbit	No significant irritation
Aromatic amine	Rabbit	No significant irritation
Methyacrylated amine	Rabbit	Corrosive
BHT	Rabbit	Mild irritant

Skin Sensitisation

Name	Species	Value
Methacrylate (HEMA)	Human and animal	Sensitising
Dimethacrylate (Bis-GMA)	Mouse	Not classified
Ethyl alcohol	Human	Not classified
Phosphorylated methacrylate	Mouse	Sensitising
Silane treated silica	Human and animal	Not classified
Aromatic amine		Not classified

Methyacrylated amine	Guinea pig	Sensitising
BHT	Human	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
Methacrylate (HEMA)	In vivo	Not mutagenic
Methacrylate (HEMA)	In Vitro	Some positive data exist, but the data are not sufficient for classification
Dimethacrylate (Bis-GMA)	In Vitro	Not mutagenic
Ethyl alcohol	In Vitro	Some positive data exist, but the data are not sufficient for classification
Ethyl alcohol	In vivo	Some positive data exist, but the data are not sufficient for classification
Phosphorylated methacrylate	In Vitro	Not mutagenic
Silane treated silica	In Vitro	Not mutagenic
Aromatic amine	In vivo	Not mutagenic
Aromatic amine	In Vitro	Some positive data exist, but the data are not sufficient for classification
Methyacrylated amine	In vivo	Not mutagenic
Methyacrylated amine	In Vitro	Some positive data exist, but the data are not sufficient for classification
BHT	In Vitro	Not mutagenic
BHT	In vivo	Not mutagenic

Carcinogenicity

Name	Route	Species	Value
Ethyl alcohol	Ingestion	Multiple animal species	Some positive data exist, but the data are not sufficient for classification
Silane treated silica	Not specified.	Mouse	Some positive data exist, but the data are not sufficient for classification
BHT	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
Methacrylate (HEMA)	Ingestion	Not classified for female reproduction	Rat	NOAEL 1,000 mg/kg/day	premating & during gestation
Methacrylate (HEMA)	Ingestion	Not classified for male reproduction	Rat	NOAEL 1,000 mg/kg/day	49 days
Methacrylate (HEMA)	Ingestion	Not classified for development	Rat	NOAEL 1,000 mg/kg/day	premating & during gestation
Dimethacrylate (Bis-GMA)	Ingestion	Not classified for development	Rat	NOAEL 1,000 mg/kg/day	during gestation
Ethyl alcohol	Inhalation	Not classified for development	Rat	NOAEL 38 mg/l	during gestation
Ethyl alcohol	Ingestion	Not classified for development	Rat	NOAEL 5,200 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
Aromatic amine	Ingestion	Not classified for female reproduction	Rat	NOAEL 600 mg/kg/day	premating into lactation
Aromatic amine	Ingestion	Not classified for development	Rat	NOAEL 50 mg/kg/day	premating into lactation
Aromatic amine	Ingestion	Toxic to male reproduction	Rat	NOAEL 50 mg/kg/day	53 days
Methyacrylated amine	Ingestion	Not classified for female reproduction	Rat	NOAEL 1,000 mg/kg/day	premating into lactation
Methyacrylated amine	Ingestion	Not classified for male reproduction	Rat	NOAEL 1,000 mg/kg/day	43 days
Methyacrylated amine	Ingestion	Not classified for development	Rat	NOAEL 200 mg/kg/day	premating into

					lactation
BHT	Ingestion	Not classified for female reproduction	Rat	NOAEL 500 mg/kg/day	2 generation
BHT	Ingestion	Not classified for male reproduction	Rat	NOAEL 500 mg/kg/day	2 generation
BHT	Ingestion	Not classified for development	Rat	NOAEL 100 mg/kg/day	2 generation

Target Organ(s)

Specific Target Organ Toxicity - single exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Ethyl alcohol	Inhalation	respiratory irritation	Some positive data exist, but the data are not sufficient for classification	Human	LOAEL 9.4 mg/l	not available
Ethyl alcohol	Inhalation	central nervous system depression	Not classified	Human and animal	NOAEL not available	
Ethyl alcohol	Ingestion	central nervous system depression	Not classified	Multiple animal species	NOAEL not available	
Ethyl alcohol	Ingestion	kidney and/or bladder	Not classified	Dog	NOAEL 3,000 mg/kg	
Phosphorylated methacrylate	Inhalation	respiratory irritation	Some positive data exist, but the data are not sufficient for classification	similar health hazards	NOAEL Not available	
Polymeric acid	Ingestion	nervous system	Not classified	Rat	NOAEL 5,000 mg/kg	
Methyacrylated amine	Inhalation	respiratory irritation	Some positive data exist, but the data are not sufficient for classification	similar health hazards	NOAEL Not available	

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Dimethacrylate (Bis-GMA)	Ingestion	endocrine system | hematopoietic system | liver | heart | skin | gastrointestinal tract | bone, teeth, nails, and/or hair | immune system | muscles | nervous system | eyes | kidney and/or bladder | respiratory system | vascular system	Not classified	Rat	NOAEL 1,000 mg/kg/day	90 days
Ethyl alcohol	Inhalation	liver	Some positive data exist, but the data are not sufficient for classification	Rabbit	LOAEL 124 mg/l	365 days
Ethyl alcohol	Inhalation	hematopoietic system | immune system	Not classified	Rat	NOAEL 25 mg/l	14 days
Ethyl alcohol	Ingestion	liver	Some positive data exist, but the data are not sufficient for classification	Rat	LOAEL 8,000 mg/kg/day	4 months
Ethyl alcohol	Ingestion	kidney and/or bladder	Not classified	Dog	NOAEL 3,000 mg/kg/day	7 days
Silane treated silica	Inhalation	respiratory system | silicosis	Not classified	Human	NOAEL Not available	occupational exposure
Polymeric acid	Ingestion	endocrine system | hematopoietic system | liver	Not classified	Rat	NOAEL 200 mg/kg/day	28 days
Polymeric 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
Aromatic amine	Ingestion	hematopoietic system	Some positive data exist, but the data are not sufficient for classification	Rat	NOAEL 74 mg/kg/day	28 days
Aromatic amine	Ingestion	liver | heart | endocrine system | gastrointestinal tract | bone, teeth, nails, and/or hair |	Not classified	Rat	NOAEL 900 mg/kg/day	28 days

		immune system | muscles | nervous system | eyes | kidney and/or bladder | respiratory system | vascular system				
Methyacrylated amine	Inhalation	heart | endocrine system | gastrointestinal tract | hematopoietic system | liver | immune system | kidney and/or bladder | respiratory system	Not classified	Rat	NOAEL 1.6 mg/l	21 days
Methyacrylated amine	Ingestion	gastrointestinal tract | immune system | nervous system | heart | skin | endocrine system | bone, teeth, nails, and/or hair | hematopoietic system | liver | muscles | eyes | kidney and/or bladder | respiratory system | vascular system	Not classified	Rat	NOAEL 500 mg/kg/day	13 weeks
BHT	Ingestion	liver	Some positive data exist, but the data are not sufficient for classification	Rat	NOAEL 250 mg/kg/day	28 days
BHT	Ingestion	kidney and/or bladder	Not classified	Rat	NOAEL 500 mg/kg/day	2 generation
BHT	Ingestion	blood	Not classified	Rat	LOAEL 420 mg/kg/day	40 days
BHT	Ingestion	endocrine system	Not classified	Rat	NOAEL 25 mg/kg/day	2 generation
BHT	Ingestion	heart	Not classified	Mouse	NOAEL 3,480 mg/kg/day	10 weeks

Aspiration Hazard
For the component/components, either no data is currently available or the data is not sufficient for classification.

Please contact the address or phone number listed on the first page of the SIS for additional toxicological information on this material and/or its components.

The product was evaluated by a toxicologist to be safe for its intended use.

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
Dimethacrylate (Bis-GMA)	1565-94-2	Common Carp	Analogous Compound	96 hours	No tox obs at lmt of water sol	>100 mg/l
Dimethacrylate (Bis-GMA)	1565-94-2	Green algae	Endpoint not reached	96 hours	EC50	>100 mg/l
Dimethacrylate (Bis-GMA)	1565-94-2	Green algae	Analogous Compound	96 hours	EC10	1.1 mg/l
Dimethacrylate (Bis-GMA)	1565-94-2	Activated sludge	Analogous Compound	3 hours	EC50	>100 mg/l

Methacrylate (HEMA)	868-77-9	Turbot	Analogous Compound	96 hours	LC50	833 mg/l
Methacrylate (HEMA)	868-77-9	Fathead minnow	Experimental	96 hours	LC50	227 mg/l
Methacrylate (HEMA)	868-77-9	Green algae	Experimental	72 hours	EC50	710 mg/l
Methacrylate (HEMA)	868-77-9	Water flea	Experimental	48 hours	EC50	380 mg/l
Methacrylate (HEMA)	868-77-9	Green algae	Experimental	72 hours	NOEC	160 mg/l
Methacrylate (HEMA)	868-77-9	Water flea	Experimental	21 days	NOEC	24.1 mg/l
Methacrylate (HEMA)	868-77-9		Experimental	16 hours	EC0	>3,000 mg/l
Methacrylate (HEMA)	868-77-9		Experimental	18 hours	LD50	<98 mg per kg of bodyweight
Phosphorylated methacrylate	1207736-18-2	Green algae	Experimental	72 hours	EC50	0.718 mg/l
Phosphorylated methacrylate	1207736-18-2	Water flea	Experimental	48 hours	EL50	>104 mg/l
Phosphorylated methacrylate	1207736-18-2	Green algae	Experimental	72 hours	NOEC	0.1 mg/l
Ethyl alcohol	64-17-5	Fathead minnow	Experimental	96 hours	LC50	14,200 mg/l
Ethyl alcohol	64-17-5	Fish	Experimental	96 hours	LC50	11,000 mg/l
Ethyl alcohol	64-17-5	Green algae	Experimental	72 hours	EC50	275 mg/l
Ethyl alcohol	64-17-5	Water flea	Experimental	48 hours	LC50	5,012 mg/l
Ethyl alcohol	64-17-5	Green algae	Experimental	72 hours	ErC10	11.5 mg/l
Ethyl alcohol	64-17-5	Water flea	Experimental	10 days	NOEC	9.6 mg/l
Silane treated silica	122334-95-6	Activated sludge	Estimated	3 hours	NOEC	>=1,000 mg/l
Silane treated silica	122334-95-6		Data not available or insufficient for classification			N/A
BHT	128-37-0	Activated sludge	Experimental	3 hours	EC50	>10,000 mg/l
BHT	128-37-0	Green algae	Experimental	72 hours	EC50	>0.4 mg/l
BHT	128-37-0	Water flea	Experimental	48 hours	EC50	0.48 mg/l
BHT	128-37-0	Zebra Fish	Experimental	96 hours	No tox obs at lmt of water sol	>100 mg/l
BHT	128-37-0	Green algae	Experimental	72 hours	EC10	0.4 mg/l
BHT	128-37-0	Medaka	Experimental	42 days	NOEC	0.053 mg/l
BHT	128-37-0	Water flea	Experimental	21 days	NOEC	0.023 mg/l
Polymeric acid	25948-33-8		Data not available or insufficient for classification			N/A
Aromatic amine	10287-53-3	Activated sludge	Experimental	3 hours	EC50	>1,000 mg/l
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	ErC10	0.71 mg/l

Camphorquinone	10373-78-1		Data not available or insufficient for classification			N/A
Methyacrylated amine	2867-47-2	Bacteria	Experimental	18 hours	EC10	42.7 mg/l
Methyacrylated amine	2867-47-2	Green algae	Experimental	72 hours	EC50	69.7 mg/l
Methyacrylated amine	2867-47-2	Medaka	Experimental	96 hours	LC50	19 mg/l
Methyacrylated amine	2867-47-2	Water flea	Experimental	48 hours	EC50	33 mg/l
Methyacrylated amine	2867-47-2	Green algae	Experimental	72 hours	NOEC	32 mg/l
Methyacrylated amine	2867-47-2	Water flea	Experimental	21 days	NOEC	4.35 mg/l

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Dimethacrylate (Bis-GMA)	1565-94-2	Analogous Compound Biodegradation	28 days	BOD	21 %BOD/ThBOD	similar to OECD 301F
Methacrylate (HEMA)	868-77-9	Experimental Hydrolysis		Hydrolytic half-life basic pH	10.9 days (t 1/2)	OECD 111 Hydrolysis func of pH
Methacrylate (HEMA)	868-77-9	Experimental Biodegradation	28 days	BOD	84 %BOD/COD	OECD 301D - Closed bottle test
Phosphorylated methacrylate	1207736-18-2	Experimental Biodegradation	28 days	BOD	77-80 %BOD/ThBOD	OECD 301F - Manometric respirometry
Ethyl alcohol	64-17-5	Experimental Biodegradation	14 days	BOD	89 %BOD/ThBOD	OECD 301C - MITI test (I)
Silane treated silica	122334-95-6	Data not availbl-insufficient	N/A	N/A	N/A	N/A
BHT	128-37-0	Data not availbl-insufficient	N/A	N/A	N/A	N/A
Polymeric acid	25948-33-8	Data not availbl-insufficient	N/A	N/A	N/A	N/A
Aromatic amine	10287-53-3	Experimental Biodegradation	28 days	CO2 evolution	40 %CO2 evolution/THCO2 evolution	OECD 301B - Modified sturm or CO2
Camphorquinone	10373-78-1	Estimated Biodegradation	28 days	BOD	20.6 %BOD/ThBOD	OECD 301C - MITI test (I)
Methyacrylated amine	2867-47-2	Estimated Photolysis		Photolytic half-life (in air)	3.88 hours (t 1/2)	Non-standard method
Methyacrylated amine	2867-47-2	Experimental Hydrolysis		Hydrolytic half-life	4.5 days (t 1/2)	Non-standard method
Methyacrylated amine	2867-47-2	Experimental Biodegradation	28 days	Dissolv. Organic Carbon Deplet	95.3 % weight	OECD 301E - Modif. OECD Screen

12.3 : Bioaccumulative potential

Material	Cas No.	Test type	Duration	Study Type	Test result	Protocol
Dimethacrylate (Bis-GMA)	1565-94-2	Modeled Bioconcentration		Bioaccumulation factor	5.8	Catalogic™
Dimethacrylate (Bis-GMA)	1565-94-2	Analogous Compound Bioconcentration		Log Kow	4.63	OECD 117 log Kow HPLC method
Methacrylate (HEMA)	868-77-9	Experimental Bioconcentration		Log Kow	0.42	OECD 107 log Kow shke flsk mtd
Phosphorylated methacrylate	1207736-18-2	Modeled Bioconcentration		Log Kow	-2.02	ACD/Labs ChemSketch™
Ethyl alcohol	64-17-5	Experimental Bioconcentration		Log Kow	-0.35	Non-standard method
Silane treated silica	122334-95-6	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
BHT	128-37-0	Experimental BCF -	56 days	Bioaccumulation	1277	OECD 305E -

		Carp		factor		Bioaccumulation flow-through fish test
Polymeric acid	25948-33-8	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Aromatic amine	10287-53-3	Experimental Bioconcentration		Log Kow	3.2	Non-standard method
Camphorquinone	10373-78-1	Estimated Bioconcentration		Bioaccumulation factor	7.1	Estimated: Bioconcentration factor
Methyacrylated amine	2867-47-2	Experimental Bioconcentration		Log Kow	1.13	Non-standard method

12.4. Mobility in soil

Material	Cas No.	Test type	Study Type	Test result	Protocol
Methacrylate (HEMA)	868-77-9	Experimental Mobility in Soil	Koc	42.7 l/kg	
Camphorquinone	10373-78-1	Estimated Mobility in Soil	Koc	20 l/kg	Episuite™

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 or ID number	UN1133	UN1133	UN1133
14.2 UN proper shipping name	ADHESIVES	ADHESIVES	ADHESIVES
14.3 Transport hazard class(es)	3	3	3

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 Marine Transport in bulk according to IMO instruments	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 Classification Code	F1	Not applicable.	Not applicable.
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

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

H225	Highly flammable liquid and vapour.
H226	Flammable liquid and vapour.
H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H360F	May damage fertility.
H400	Very toxic to aquatic life.

H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

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