

Safety Information Sheet for Medical Devices

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Transportation version number: 1.00 (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

3MTM ESPETM ScotchbondTM Universal

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

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

Page: 1of 13

23/10/2019

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

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) |

Pictograms



Ingredients:

Ingredient	CAS Nbr	EC No.	% by Wt
Bis-GMA	1565-94-2	216-367-7	15 - 25
Hydroxylethyl Methacrylate (HEMA)	868-77-9	212-782-2	15 - 25
Methacrylic phosphoric acid	1207736-18-2		10 - 20
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.

PRECAUTIONARY STATEMENTS

Prevention:

P210A 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.

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

carbon dioxide to extinguish.

Notes on labelling

Per test data, this product is not classified as H314.

Page: 2of 13

2.3. Other hazards

For information on hazards and safe use, please consider the corresponding sections of this document.

SECTION 3: Composition/information on ingredients

Ingredient	CAS Nbr	EC No.	% by Wt	Classification
Bis-GMA	1565-94-2	216-367-7	15 - 25	Skin Sens. 1B, H317
Hydroxylethyl Methacrylate (HEMA) (REACH Reg. No.:01- 2119490169-29)	868-77-9	212-782-2	15 - 25	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317 - Nota D
Methacrylic phosphoric acid	1207736-18-2		10 - 20	Skin Corr. 1B, H314; Eye Dam. 1, H318; Skin Sens. 1, H317; STOT SE 3, H335
Water	7732-18-5	231-791-2	10 - 15	Substance not classified as hazardous
Ethanol (REACH Reg. No.:01-2119457610-43)	64-17-5	200-578-6	10 - 15	Flam. Liq. 2, H225 Eye Irrit. 2, H319
Silane treated silica	122334-95-6	310-178-4	7 - 13	Substance not classified as hazardous
Polymeric acid	25948-33-8		1 - 5	Substance not classified as hazardous
Camphorquinone	10373-78-1	233-814-1	< 2	Substance not classified as hazardous
Aromatic amine	10287-53-3	233-634-3	< 2	Aquatic Chronic 2, H411
Methyacrylated amine	2867-47-2	220-688-8	< 1	Acute Tox. 4, H312; Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317 - Nota D
BHT (REACH Reg. No.:01- 2119565113-46)	128-37-0	204-881-4	0.01 - 0.5	Aquatic Acute 1, H400,M=1; Aquatic Chronic 1, H410,M=1

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

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

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation

Remove person to fresh air. If you feel unwell, get medical attention.

Skin contact

Immediately wash with soap and water. Remove contaminated clothing and wash before reuse. If signs/symptoms develop, get medical attention.

Eye contact

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.

Page: 3of 13

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

SubstanceConditionFormaldehydeDuring 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 designed for use on solvents, such as alcohols and acetone, that can dissolve in water. An AR-AFFF type foam is recommended. 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

Page: 4of 13

23/10/2019

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

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 information sheet.

8.2. Exposure controls

8.2.1. Engineering controls

Use in a well-ventilated area.

8.2.2. Personal protective equipment (PPE)

Eye/face protection

Select and use eye/face protection to prevent contact based on the results of an exposure assessment. The following eye/face protection(s) are recommended:

Safety glasses with side shields.

Applicable Norms/Standards

Use eye protection conforming to EN 166

Skin/hand protection

See Section 7.1 for additional information on skin protection.

Respiratory protection

None required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical stateLiquid.ColourYellow

Specific Physical Form:Viscous LiquidOdorCharacteristic OdourpHNot applicable.Boiling point/boiling range>= 78 °C

Boiling point/boiling range >= 78 °C **Melting point**No data available.

Melting pointNo data availableFlammability (solid, gas)Not applicableExplosive propertiesNot classifiedOxidising propertiesNot classified

Flash point 30.5 °C [Test Method:Closed Cup]

Autoignition temperatureNo data available.Flammable Limits(LEL)No data available.

Page: 5of 13

3MTM ESPETM ScotchbondTM Universal

23/10/2019

Flammable Limits(UEL)

No data available.

Relative density 1 - 1.2 [*Ref Std*:WATER=1]

Water solubilityAppreciableViscosityNot applicable.Density1 - 1.2 g/cm3

9.2. Other information

EU Volatile Organic Compounds

No data available.

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

<u>Substance</u> <u>Condition</u>

None known.

Refer to section 5.2 for hazardous decomposition products during combustion.

SECTION 11: Toxicological information

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

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

Page: 6of 13

(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.

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
Hydroxylethyl Methacrylate (HEMA)	Dermal	Rabbit	LD50 > 5,000 mg/kg
Hydroxylethyl Methacrylate (HEMA)	Ingestion	Rat	LD50 5,564 mg/kg
Bis-GMA	Ingestion		LD50 estimated to be 2,000 - 5,000 mg/kg
Bis-GMA	Dermal	Professional judgement	LD50 estimated to be 2,000 - 5,000 mg/kg
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
Methacrylic phosphoric acid	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Methacrylic phosphoric acid	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

Page: 7of 13

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Overall product	Rabbit	No significant irritation
Hydroxylethyl Methacrylate (HEMA)	Rabbit	Minimal irritation
Bis-GMA	Not available	Minimal irritation
Ethanol	Rabbit No significant irritation	
Methacrylic phosphoric acid	In vitro data	Corrosive
Silane treated silica	Rabbit No significant irritation	
Aromatic amine	Rabbit	No significant irritation
BHT	Human and animal	Minimal irritation

Serious Eye Damage/Irritation

Name	Species Value	
Overall product	In vitro data	Corrosive
Hydroxylethyl Methacrylate (HEMA)	Rabbit	Moderate irritant
Bis-GMA	Not available	Moderate irritant
Ethanol	Rabbit	Severe irritant
Methacrylic phosphoric acid	In vitro data	Corrosive
Silane treated silica	Rabbit	No significant irritation
Aromatic amine	Rabbit	Mild irritant
BHT	Rabbit	Mild irritant

Skin Sensitisation

Name	Species	Value
Hydroxylethyl Methacrylate (HEMA)	Human and animal	Sensitising
Bis-GMA	Guinea pig	Sensitising
Ethanol	Human	Not classified
Methacrylic phosphoric acid	Professional judgement	Sensitising
Silane treated silica	Human and animal	Not classified
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
Hydroxylethyl Methacrylate (HEMA)	In vivo	Not mutagenic
Hydroxylethyl Methacrylate (HEMA)	In Vitro	Some positive data exist, but the data are not sufficient for classification
Bis-GMA	In Vitro	Some positive data exist, but the data are not sufficient for classification
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
Methacrylic phosphoric acid	In Vitro	Not mutagenic
Silane treated silica	In Vitro	Not mutagenic
BHT	In Vitro	Not mutagenic
BHT	In vivo	Not mutagenic

Carcinogenicity

Name	Route	Species	Value
Ethanol	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

Page: 8of 13

Reproductive and/or Developmental Effects

Name	Route	Value	Species	Test result	Exposure Duration
Hydroxylethyl Methacrylate	Ingestion	Not classified for female	Rat	NOAEL 1,000	premating & during
(HEMA)		reproduction		mg/kg/day	gestation
Hydroxylethyl Methacrylate	Ingestion	Not classified for male	Rat	NOAEL 1,000	49 days
(HEMA)		reproduction		mg/kg/day	
Hydroxylethyl Methacrylate	Ingestion	Not classified for development	Rat	NOAEL 1,000	premating & during
(HEMA)				mg/kg/day	gestation
Bis-GMA	Ingestion	Not classified for female	Mouse	NOAEL 0.8	premating & during
		reproduction		mg/kg/day	gestation
Bis-GMA	Ingestion	Not classified for male	Mouse	NOAEL 0.8	premating & during
		reproduction		mg/kg/day	gestation
Bis-GMA	Ingestion	Not classified for development	Mouse	NOAEL 0.8	premating & during
				mg/kg/day	gestation
Ethanol	Inhalation	Not classified for development	Rat	NOAEL 38 mg/l	during gestation
Ethanol	Ingestion	Not classified for development	Rat	NOAEL 5,200	premating & during
				mg/kg/day	gestation
Silane treated silica	Ingestion	Not classified for female	Rat	NOAEL 509	1 generation
		reproduction		mg/kg/day	
Silane treated silica	Ingestion	Not classified for male	Rat	NOAEL 497	1 generation
		reproduction		mg/kg/day	
Silane treated silica	Ingestion	Not classified for development	Rat	NOAEL 1,350	during
				mg/kg/day	organogenesis
BHT	Ingestion	Not classified for female	Rat	NOAEL 500	2 generation
		reproduction		mg/kg/day	
BHT	Ingestion	Not classified for male	Rat	NOAEL 500	2 generation
		reproduction		mg/kg/day	
BHT	Ingestion	Not classified for development	Rat	NOAEL 100	2 generation
				mg/kg/day	

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	
Methacrylic phosphoric acid	Inhalation	respiratory irritation	May cause respiratory irritation	similar health hazards	NOAEL Not available	
Polymeric acid	Ingestion	nervous system	Not classified	Rat	NOAEL 5,000 mg/kg	

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration	
Bis-GMA	Ingestion	endocrine system liver nervous system kidney and/or bladder	Not classified	Mouse	NOAEL 0.8 mg/kg/day	premating & during gestation	
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	Rat	LOAEL 8,000	4 months	

Page: 9of 13

			classification		mg/kg/day	
Ethanol	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
ВНТ	Ingestion	liver	Some positive data exist, but the data are not sufficient for classification	Rat	NOAEL 250 mg/kg/day	28 days
ВНТ	Ingestion	kidney and/or bladder	Not classified	Rat	NOAEL 500 mg/kg/day	2 generation
ВНТ	Ingestion	blood	Not classified	Rat	LOAEL 420 mg/kg/day	40 days
ВНТ	Ingestion	endocrine system	Not classified	Rat	NOAEL 25 mg/kg/day	2 generation
ВНТ	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.

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
Bis-GMA	1565-94-2		Data not available or insufficient for classification			
Hydroxylethyl Methacrylate (HEMA)	868-77-9	Fathead minnow	Experimental	96 hours	LC50	227 mg/l
Hydroxylethyl Methacrylate (HEMA)	868-77-9	Green algae	Experimental	72 hours	EC50	710 mg/l
Hydroxylethyl Methacrylate (HEMA)	868-77-9	Water flea	Experimental	48 hours	EC50	380 mg/l
Hydroxylethyl Methacrylate (HEMA)	868-77-9	Green Algae	Experimental	72 hours	NOEC	160 mg/l

Page: 10of 13

Hydroxylethyl Methacrylate (HEMA)	868-77-9	Water flea	Experimental	21 days	NOEC	24.1 mg/l
Methacrylic phosphoric	1207736-18-2	+	Data not available			
acid	1207730 10 2		or insufficient for classification			
Ethanol	64-17-5	Rainbow trout	Experimental	96 hours	LC50	42 mg/l
Ethanol	64-17-5	Water flea	Experimental	48 hours	LC50	5,012 mg/l
Ethanol	64-17-5	Algae other	Experimental	96 hours	NOEC	1,580 mg/l
Ethanol	64-17-5	Water flea	Experimental	10 days	NOEC	9.6 mg/l
Silane treated silica	122334-95-6		Data not available or insufficient for classification			
Polymeric acid	25948-33-8		Data not available or insufficient for classification			
Aromatic amine	10287-53-3	Green Algae	Experimental	72 hours	EC50	2.8 mg/l
Aromatic amine	10287-53-3	Rainbow trout	Experimental	96 hours	LC50	1.9 mg/l
Aromatic amine	10287-53-3	Water flea	Experimental	48 hours	EC50	4.5 mg/l
Aromatic amine	10287-53-3	Green Algae	Experimental	72 hours	Effect Conc. 10% - Growth Rate	0.71 mg/l
Camphorquinone	10373-78-1		Data not available or insufficient for classification			
Methyacrylated amine	2867-47-2	Green Algae	Experimental	72 hours	EC50	69.7 mg/l
Methyacrylated amine	2867-47-2	Ricefish	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
ВНТ	128-37-0	Green algae	Experimental	72 hours	EC50	>0.4 mg/l
ВНТ	128-37-0	Water flea	Experimental	48 hours	EC50	0.48 mg/l
ВНТ	128-37-0	Zebra Fish	Experimental	96 hours	LC50	>100 mg/l
ВНТ	128-37-0	Green algae	Experimental	72 hours	Effect Concentration 10%	0.4 mg/l
ВНТ	128-37-0	Ricefish	Experimental	42 days	NOEC NOEC	0.053 mg/l
ВНТ	128-37-0	Water flea	Experimental	21 days	NOEC	0.023 mg/l

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Bis-GMA	1565-94-2	Estimated Biodegradation	28 days	BOD	32 % weight	OECD 301C - MITI test (I)
Hydroxylethyl Methacrylate (HEMA)	868-77-9	Experimental Biodegradation	14 days	BOD	95 % BOD/ThBOD	OECD 301C - MITI test (I)
Methacrylic phosphoric acid	1207736-18-2	Estimated Biodegradation	28 days	BOD	91 % weight	OECD 301C - MITI test (I)
Ethanol	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	

Page: 11of 13

Polymeric acid	25948-33-8	Data not availbl- insufficient			N/A	
Aromatic amine	10287-53-3	Experimental Biodegradation	28 days	CO2 evolution	40 %CO2 evolution/THC O2 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)	Other methods
Methyacrylated amine	2867-47-2	Experimental Hydrolysis		Hydrolytic half-life	4.5 days (t 1/2)	Other methods
Methyacrylated amine	2867-47-2	Experimental Biodegradation	28 days	Dissolv. Organic Carbon Deplet	95.3 % weight	OECD 301E - Modified OECD Scre
ВНТ	128-37-0	Data not availbl- insufficient			N/A	

12.3 : Bioaccumulative potential

Material	Cas No.	Test type	Duration	Study Type	Test result	Protocol
Bis-GMA	1565-94-2	Estimated Bioconcentration		Bioaccumulation factor	5.8	Estimated: Bioconcentration factor
Hydroxylethyl Methacrylate (HEMA)	868-77-9	Experimental Bioconcentration		Log Kow	0.42	Other methods
Methacrylic phosphoric acid	1207736-18-2	Estimated Bioconcentration		Bioaccumulation factor	4.5	Other methods
Ethanol	64-17-5	Experimental Bioconcentration		Log Kow	-0.35	Other methods
Silane treated silica	122334-95-6	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
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	Other methods
Camphorquinone	10373-78-1	Estimated Bioconcentration		Bioaccumulation factor	7.1	Estimated: Bioconcentration factor
Methyacrylated amine	2867-47-2	Experimental Bioconcentration		Log Kow	1.13	Other methods
ВНТ	128-37-0	Experimental BCF- Carp	56 days	Bioaccumulation factor	1277	OECD 305E - Bioaccumulation flow- through fish test

12.4. Mobility in soil

Please contact manufacturer for more details

12.5. Results of the PBT and vPvB assessment

This material does not contain any substances that are assessed to be a PBT or vPvB

12.6. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Dispose of contents/ container in accordance with the local/regional/national/international regulations.

Refer to Instructions for Use (IFU) for more information.

EU waste code (product as sold)

180106* Chemicals consisting of or containing dangerous substances.

SECTION 14: Transportation information

ADR: UN1133; ADHESIVES; 3; III; (D/E); F1.

IATA: UN1133; ADHESIVES; 3; III.

IMDG: UN1133; ADHESIVES; 3; III; FE, SD.

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.
H335	May cause respiratory irritation.
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.

Revision information:

Revision information not available

The product to which this Safety Information Sheet applies is classified as a medical device according to the EU Medical Device Regulation EU 2017/745. _x000D_

Medical devices which are invasive or used in direct physical contact with the human body are exempt from the requirements of classification and labelling according to Regulation (EC) No. 1272/2008 (CLP; Article 1, paragraph 5)._x000D_

The EU Medical Device Regulation does not foresee the use of Safety Data sheets for medical devices which are invasive or used in direct physical contact with the human body, as the safe use of the product is described through the Instructions for Use and /or the labelling for the product. Nevertheless, the 3M Safety Information Sheet is provided as a further service to customers to provide additional toxicology and chemical information on the product. In case of further questions, please contact your 3M representative listed on the Safety Information Sheet.

3M United Kingdom Safety Information Sheets are available at www.3M.com/uk

Page: 13of 13