



Safety Information Sheet for Medical Devices

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Document group:	29-9060-4	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™ RelyX™ Ultimate Refill (56887, 56888, 56889, 56890)

Product Identification Numbers

70-2011-3865-1

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:

29-9001-8, 29-9002-6

TRANSPORTATION INFORMATION

70-2011-3865-1

Component 1

ADR/RID: UN3077, NOT RESTRICTED AS PER SPECIAL PROVISION 375, ENVIRONMENTALLY HAZARDOUS SUBSTANCE EXEMPTION, (2-PROPENOIC ACID, 2-METHYL-, 1,12-DODECANEDIYL ESTER), III, --.

IMDG-CODE: UN3077, NOT RESTRICTED AS PER IMDG CODE 2.10.2.7, MARINE POLLUTANT EXCEPTION, (2-PROPENOIC ACID, 2-METHYL-, 1,12-DODECANEDIYL ESTER), III, IMDG-Code segregation code: NONE, EMS: --.

ICAO/IATA: UN3077, NOT RESTRICTED AS PER SPECIAL PROVISION A197, ENVIRONMENTALLY HAZARDOUS SUBSTANCE EXEMPTION, (2-PROPENOIC ACID, 2-METHYL-, 1,12-DODECANEDIYL ESTER), III.

Component 2

ADR/RID: UN3077, NOT RESTRICTED AS PER SPECIAL PROVISION 375, ENVIRONMENTALLY HAZARDOUS SUBSTANCE EXEMPTION, (TERT-BUTYL PEROXY-3,5,5-TRIMETHYLHEXANOATE, 95%, (ACETIC ACID, COPPER (2+) SALT, MONOHYDRATE), III, --.

IMDG-CODE: UN3077, NOT RESTRICTED AS PER IMDG CODE 2.10.2.7, MARINE POLLUTANT EXCEPTION, (TERT-BUTYL PEROXY-3,5,5-TRIMETHYLHEXANOATE, 95%, (ACETIC ACID, COPPER (2+) SALT, MONOHYDRATE), III, IMDG-Code segregation code: NONE, EMS: --.

ICAO/IATA: UN3077, NOT RESTRICTED AS PER SPECIAL PROVISION A197, ENVIRONMENTALLY HAZARDOUS SUBSTANCE EXEMPTION, (TERT-BUTYL PEROXY-3,5,5-TRIMETHYLHEXANOATE, 95%, (ACETIC ACID, COPPER (2+) SALT, MONOHYDRATE), III.

ADR/IATA/IMDG: Not restricted for transport.

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

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Document group:	29-9001-8	Version number:	2.00
Revision date:	15/02/2023	Supersedes date:	06/12/2019

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™ RelyX™ Ultimate Base Paste

Product Identification Numbers

LE-F100-1018-8

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

The retained CLP Regulation (EU) No 1272/2008 as amended for Great Britain

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.

A similar mixture has been tested for eye damage/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 SI 2002 No 618, as amended (UK MDR 2002), 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 the retained CLP Regulation (EC) No. 1272/2008, as

amended for Great Britain (Article 1, paragraph 5). Although not required, the classification and label information, as applicable, is provided below.

CLASSIFICATION:

Skin Sensitization, Category 1 - Skin Sens. 1; H317

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

The retained CLP Regulation (EU) No 1272/2008 as amended for Great Britain

SIGNAL WORD

WARNING.

Symbols

GHS07 (Exclamation mark) |

Pictograms**HAZARD STATEMENTS:**

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

PRECAUTIONARY STATEMENTS**Prevention:**

P280E Wear protective gloves.

Response:

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

2.3. Other hazards

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

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], as amended for GB
Silane teated glass powder	(CAS-No.) None	50 - 60	Substance not classified as hazardous
Phosphorylated methacrylate	(CAS-No.) 1224866-76-5	20 - 30	Eye Dam. 1, H318

Phosphorylated methacrylate	(EC-No.) 700-757-3	20 - 30	Eye Dam. 1, H318
Triethyleneglycol dimethacrylate (TEGDMA)	(CAS-No.) 109-16-0 (EC-No.) 203-652-6	10 - 20	Skin Sens. 1, H317
Persulfate	(CAS-No.) 7775-27-1 (EC-No.) 231-892-1	< 1	Ox. Sol. 3, H272 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Resp. Sens. 1, H334 Skin Sens. 1, H317 STOT SE 3, H335 Acute Tox. 4, H302
Silane treated silica	(CAS-No.) 68909-20-6 (EC-No.) 272-697-1	5 - 10	Substance with a national occupational exposure limit
Perester	(CAS-No.) 13122-18-4 (EC-No.) 236-050-7	< 0.5	Org. Perox. CD, H242 Aquatic Acute 1, H400,M=1 Aquatic Chronic 1, H410,M=1 Skin Sens. 1B, H317
Glass powder	(CAS-No.) 65997-17-3 (EC-No.) 266-046-0	< 3	Substance not classified as hazardous
Copper salt	(CAS-No.) 6046-93-1	< 0.1	Acute Tox. 4, H302 Skin Corr. 1B, H314 Eye Dam. 1, H318 Aquatic Acute 1, H400,M=10 Aquatic Chronic 1, H410,M=10

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

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

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation

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

Skin contact

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

Eye contact

Flush with large amounts of water. Remove contact lenses if easy to do. Continue rinsing. If signs/symptoms persist, get medical attention.

If swallowed

Rinse mouth. If you feel unwell, get medical attention.

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

In case of fire: Use a fire fighting agent suitable for ordinary combustible material such as water or foam to extinguish.

5.2. Special hazards arising from the substance or mixture

None inherent in this product.

Hazardous Decomposition or By-Products

<u>Substance</u>	<u>Condition</u>
Carbon monoxide	During combustion.
Carbon dioxide.	During combustion.
Irritant vapours or gases.	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

Collect as much of the spilled material as possible. Place in a closed container approved for transportation by appropriate authorities. Clean up residue. 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
Silicon dioxide	68909-20-6	UK HSC	TWA(as respirable dust):2.4 mg/m ³ ;TWA(as inhalable dust):6 mg/m ³	

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	Solid.
Specific Physical Form:	Paste
Colour	Tooth
Odor	Slight Acrylic
Melting point/freezing point	No data available.
Boiling point/boiling range	No data available.
Flammability (solid, gas)	Not classified
Flammable Limits(LEL)	No data available.
Flammable Limits(UEL)	No data available.
Flash point	No flash point
Autoignition temperature	No data available.
Relative density	2 - 2.2 [Ref Std: WATER=1]
pH	substance/mixture is non-soluble (in water)
Kinematic Viscosity	No data available.
Water solubility	Negligible
Density	2 g/cm ³ - 2.2 g/cm ³

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 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

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 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 hazard classes as defined in the retained CLP Regulation (EU) No 1272/2008, as amended for Great Britain.

Signs and Symptoms of Exposure

Based on test data and/or information on the components, this material may produce the following health effects:

Inhalation

This product may have a characteristic odour; however, no adverse health effects are anticipated.

Skin contact

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

Eye contact

Contact with the eyes during product use is not expected to result in significant irritation.

Ingestion

May be harmful if swallowed.

Gastrointestinal irritation: Signs/symptoms may include abdominal pain, stomach upset, nausea, vomiting and diarrhoea.

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 ATE >2,000 - =5,000 mg/kg
Silane teated glass powder	Dermal		LD50 estimated to be > 5,000 mg/kg
Silane teated glass powder	Ingestion		LD50 estimated to be 2,000 - 5,000 mg/kg
Phosphorylated methacrylate	Dermal		LD50 estimated to be > 5,000 mg/kg
Phosphorylated methacrylate	Ingestion	Rat	LD50 > 2,000 mg/kg
Triethyleneglycol dimethacrylate (TEGDMA)	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Triethyleneglycol dimethacrylate (TEGDMA)	Ingestion	Rat	LD50 10,837 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
Glass powder	Dermal		LD50 estimated to be > 5,000 mg/kg
Glass powder	Ingestion		LD50 estimated to be 2,000 - 5,000 mg/kg
Persulfate	Dermal	Rabbit	LD50 > 10,000 mg/kg
Persulfate	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 47.93 mg/l
Persulfate	Ingestion	Rat	LD50 895 mg/kg
Perester	Dermal	Rat	LD50 > 2,000 mg/kg
Perester	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 0.8 mg/l
Perester	Ingestion	Rat	LD50 12,905 mg/kg
Copper salt	Dermal	Rat	LD50 > 2,000 mg/kg
Copper salt	Ingestion	Rat	LD50 > 300, < 2000 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Silane teated glass powder	Professional judgement	No significant irritation
Phosphorylated methacrylate	Rabbit	Minimal irritation
Triethyleneglycol dimethacrylate (TEGDMA)	Guinea pig	Mild irritant
Silane treated silica	Rabbit	No significant irritation
Glass powder	Professional judgement	No significant irritation
Perester	Rabbit	No significant irritation
Copper salt	In vitro data	Corrosive

Serious Eye Damage/Irritation

Name	Species	Value
Overall product		No significant irritation
Silane teated glass powder	Professional judgement	No significant irritation
Phosphorylated methacrylate	Rabbit	Corrosive
Triethyleneglycol dimethacrylate (TEGDMA)	Professional judgement	Moderate irritant
Silane treated silica	Rabbit	No significant irritation
Glass powder	Professional judgement	No significant irritation
Perester	Rabbit	No significant irritation
Copper salt	Rabbit	Corrosive

Skin Sensitisation

Name	Species	Value
Phosphorylated methacrylate	Guinea pig	Not classified
Triethyleneglycol dimethacrylate (TEGDMA)	Human and animal	Sensitising
Silane treated silica	Human and animal	Not classified
Perester	Guinea pig	Sensitising
Copper salt	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
Phosphorylated methacrylate	In Vitro	Not mutagenic
Triethyleneglycol dimethacrylate (TEGDMA)	In Vitro	Some positive data exist, but the data are not sufficient for classification
Silane treated silica	In Vitro	Not mutagenic

Copper salt	In Vitro	Not mutagenic
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Carcinogenicity

Name	Route	Species	Value
Triethyleneglycol dimethacrylate (TEGDMA)	Dermal	Mouse	Not carcinogenic
Silane treated silica	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
Triethyleneglycol dimethacrylate (TEGDMA)	Ingestion	Not classified for female reproduction	Mouse	NOAEL 1 mg/kg/day	1 generation
Triethyleneglycol dimethacrylate (TEGDMA)	Ingestion	Not classified for male reproduction	Mouse	NOAEL 1 mg/kg/day	1 generation
Triethyleneglycol dimethacrylate (TEGDMA)	Ingestion	Not classified for development	Mouse	NOAEL 1 mg/kg/day	1 generation
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

Target Organ(s)**Specific Target Organ Toxicity - single exposure**

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Copper salt	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
Triethyleneglycol dimethacrylate (TEGDMA)	Dermal	kidney and/or bladder blood	Not classified	Mouse	NOAEL 833 mg/kg/day	78 weeks
Silane treated silica	Inhalation	respiratory system silicosis	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 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
Silane teated glass powder	None	N/A	Data not available or insufficient for classification	N/A	N/A	N/A
Phosphorylated methacrylate	1224866-76-5	Green algae	Endpoint not reached	72 hours	EC50	>100 mg/l
Phosphorylated methacrylate	1224866-76-5	Water flea	Experimental	48 hours	EC50	>100 mg/l
Phosphorylated methacrylate	1224866-76-5	Green algae	Experimental	72 hours	NOEC	56 mg/l
Triethyleneglycol dimenthacrylate (TEGDMA)	109-16-0	Green algae	Experimental	72 hours	ErC50	>100 mg/l
Triethyleneglycol dimenthacrylate (TEGDMA)	109-16-0	Zebra Fish	Experimental	96 hours	LC50	16.4 mg/l
Triethyleneglycol dimenthacrylate (TEGDMA)	109-16-0	Green algae	Experimental	72 hours	NOEC	18.6 mg/l
Triethyleneglycol dimenthacrylate (TEGDMA)	109-16-0	Water flea	Experimental	21 days	NOEC	32 mg/l
Persulfate	7775-27-1	Algae or other aquatic plants	Estimated	72 hours	EC50	320 mg/l
Persulfate	7775-27-1	Copepod	Estimated	48 hours	EC50	21.22 mg/l
Persulfate	7775-27-1	Rainbow trout	Estimated	96 hours	LC50	76.3 mg/l
Persulfate	7775-27-1	Algae or other aquatic plants	Estimated	72 hours	NOEC	32 mg/l
Silane treated silica	68909-20-6	Algae or other aquatic plants	Estimated	72 hours	EC50	>100 mg/l
Perester	13122-18-4	Activated sludge	Experimental	3 hours	NOEC	26.3 mg/l
Perester	13122-18-4	Green algae	Experimental	N/A	EC50	0.51 mg/l
Perester	13122-18-4	Rainbow trout	Experimental	N/A	LC50	7 mg/l
Perester	13122-18-4	Water flea	Experimental	N/A	EC50	>100 mg/l
Perester	13122-18-4	Green algae	Experimental	N/A	NOEC	0.125 mg/l
Glass powder	65997-17-3	Green algae	Experimental	72 hours	EC50	>1,000 mg/l
Glass powder	65997-17-3	Water flea	Experimental	72 hours	EC50	>1,000 mg/l
Glass powder	65997-17-3	Zebra Fish	Experimental	96 hours	LC50	>1,000 mg/l
Glass powder	65997-17-3	Green algae	Experimental	72 hours	NOEC	>1,000 mg/l
Copper salt	6046-93-1	Green algae	Estimated	72 hours	EC50	0.33 mg/l
Copper salt	6046-93-1	Water flea	Estimated	48 hours	EC50	0.04 mg/l
Copper salt	6046-93-1	Zebra Fish	Estimated	96 hours	LC50	0.037 mg/l
Copper salt	6046-93-1	Fathead minnow	Estimated	32 days	EC10	0.019 mg/l
Copper salt	6046-93-1	Green algae	Estimated	N/A	NOEC	0.069 mg/l

Copper salt	6046-93-1	Water flea	Estimated	7 days	NOEC	0.01 mg/l
Copper salt	6046-93-1	Activated sludge	Estimated	N/A	EC50	22 mg/l
Copper salt	6046-93-1	Barley	Estimated	4 days	NOEC	50 mg/kg (Dry Weight)
Copper salt	6046-93-1	Bobwhite quail	Estimated	14 days	LD50	4,402 mg per kg of bodyweight
Copper salt	6046-93-1	Redworm	Estimated	56 days	NOEC	31 mg/kg (Dry Weight)
Copper salt	6046-93-1	Sediment Worm	Estimated	28 days	NOEC	57.5 mg/kg (Dry Weight)
Copper salt	6046-93-1	Soil microbes	Estimated	4 days	NOEC	38 mg/kg (Dry Weight)
Copper salt	6046-93-1	Springtail	Estimated	28 days	NOEC	87.7 mg/kg (Dry Weight)

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Silane teated glass powder	None	Data not availbl-insufficient	N/A	N/A	N/A	N/A
Phosphorylated methacrylate	1224866-76-5	Experimental Biodegradation	28 days	BOD	82 %BOD/ThOD	OECD 301F - Manometric respirometry
Triethyleneglycol dimenthacrylate (TEGDMA)	109-16-0	Experimental Biodegradation	28 days	CO2 evolution	85 %CO2 evolution/THCO2 evolution	OECD 301B - Modified sturm or CO2
Persulfate	7775-27-1	Data not availbl-insufficient	N/A	N/A	N/A	N/A
Silane treated silica	68909-20-6	Data not availbl-insufficient	N/A	N/A	N/A	N/A
Perester	13122-18-4	Estimated Biodegradation	28	BOD	14 %BOD/ThOD	OECD 301C - MITI test (I)
Glass powder	65997-17-3	Data not availbl-insufficient	N/A	N/A	N/A	N/A
Copper salt	6046-93-1	Analogous Compound Biodegradation	14 days	BOD	74 %BOD/ThOD	OECD 301C - MITI test (I)

12.3 : Bioaccumulative potential

Material	Cas No.	Test type	Duration	Study Type	Test result	Protocol
Silane teated glass powder	None	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Phosphorylated methacrylate	1224866-76-5	Experimental Bioconcentration		Log Kow	-0.2	
Triethyleneglycol dimenthacrylate (TEGDMA)	109-16-0	Experimental Bioconcentration		Log Kow	2.3	EC A.8 Partition Coefficient
Persulfate	7775-27-1	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Silane treated silica	68909-20-6	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Perester	13122-18-4	Estimated Bioconcentration		Bioaccumulation factor	363	
Glass powder	65997-17-3	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Copper salt	6046-93-1	Analogous Compound Bioconcentration		Log Kow	-0.17	

12.4. Mobility in soil

Material	Cas No.	Test type	Study Type	Test result	Protocol
Copper salt	6046-93-1	Analogous Compound Mobility in Soil	Koc	228 l/kg	

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

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

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

Not hazardous for transportation.

	Ground Transport (ADR)	Air Transport (IATA)	Marine Transport (IMDG)
14.1 UN number	No data available.	No data available.	No data available.
14.2 UN proper shipping name	No data available.	No data available.	No data available.
14.3 Transport hazard class(es)	No data available.	No data available.	No data available.
14.4 Packing group	No data available.	No data available.	No data available.
14.5 Environmental hazards	No data available.	No data available.	No data available.
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 Classification Code	No data available.	No data available.	No data available.
IMDG Segregation Code	No data available.	No data available.	No data available.

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

H242	Heating may cause a fire.
H272	May intensify fire; oxidiser.
H302	Harmful if swallowed.
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.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
H410	Very 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 Safety Information Sheets for Great Britain are available at www.3M.com/uk



Safety Information Sheet for Medical Devices

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Document group:	29-9002-6	Version number:	1.00
Revision date:	06/12/2019	Supersedes date:	Initial issue.
Transportation version number: 1.00 (06/12/2019)			

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 ESPE RelyX Ultimate Catalyst Paste

Product Identification Numbers

LE-F100-1018-9

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

Identified uses

Medical device; refer to Instructions for Use

Restrictions on Use

For use only by dental professionals.

1.3 Details of the supplier of the safety information sheet for medical devices

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

1.4. Emergency telephone number

+44 (0)1344 858 000

SECTION 2: Hazard identification

2.1. Classification of the substance or mixture

CLP REGULATION (EC) No 1272/2008

This product is a medical device as defined in Directive 93/42/EEC (MDD), which is invasive or used in direct physical contact with the human body, and therefore is exempt from the requirements of classification and labelling according to Regulation (EC) No. 1272/2008 (CLP; Article 1, paragraph 5). Although not required, the classification and label information, as applicable, is provided below.

CLASSIFICATION:

Serious Eye Damage/Eye Irritation, Category 2 - Eye Irrit. 2; H319
Skin Sensitization, Category 1 - Skin Sens. 1; H317
Hazardous to the Aquatic Environment (Acute), Category 1 - Aquatic Acute 1; H400
Hazardous to the Aquatic Environment (Chronic), Category 2 - Aquatic Chronic 2; H411

For full text of H phrases, see Section 16.

2.2. Label elements

CLP REGULATION (EC) No 1272/2008

SIGNAL WORD

WARNING.

Symbols:

GHS07 (Exclamation mark) | GHS09 (Environment) |

Pictograms



Ingredients:

Ingredient	CAS Nbr	EC No.	% by Wt
Aliphatic dimethacrylate	72829-09-5	276-900-4	< 5
Methacrylated amine	93962-71-1	300-709-8	< 2
Methacrylated amine	93962-70-0	300-708-2	< 0.5

HAZARD STATEMENTS:

H319	Causes serious eye irritation.
H317	May cause an allergic skin reaction.
H400	Very toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.

PRECAUTIONARY STATEMENTS

Prevention:

P280E	Wear protective gloves.
P273	Avoid release to the environment.

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.

Disposal:

P501	Dispose of contents/container in accordance with applicable local/regional/national/international regulations.
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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
Silane treated glass powder	None		55 - 65	Substance not classified as hazardous
Substituted dimethacrylate (REACH Reg. No.:01-2120102014-82)	27689-12-9	248-607-1	20 - 30	Aquatic Chronic 4, H413
Salt of substituted barbituric acid	945012-02-2		1 - 10	Substance not classified as hazardous
Sulfinate	824-79-3	212-538-5	< 5	Substance not classified as hazardous
Aliphatic dimethacrylate	72829-09-5	276-900-4	< 5	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335; Aquatic Acute 1, H400,M=10; Aquatic Chronic 1, H410,M=1
Silane treated silica	68909-20-6	272-697-1	< 5	Substance with a Community level exposure limit in the workplace
Methacrylated amine	93962-71-1	300-709-8	< 2	Skin Sens. 1, H317
Calcium hydroxide (REACH Reg. No.:01-2119475151-45)	1305-62-0	215-137-3	< 2	Skin Corr. 1C, H314
Methacrylated amine	93962-70-0	300-708-2	< 0.5	Skin Sens. 1, H317
Titanium dioxide (REACH Reg. No.:01-2119489379-17)	13463-67-7	236-675-5	< 0.5	Substance with a Community level exposure limit in the workplace

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. Remove contact lenses if easy to do. Continue rinsing. Get medical attention.

If swallowed

Rinse mouth. If you feel unwell, get medical attention.

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

In case of fire: Use a fire fighting agent suitable for ordinary combustible material such as water or foam to extinguish.

5.2. Special hazards arising from the substance or mixture

None inherent in this product.

Hazardous Decomposition or By-Products**Substance**

Carbon monoxide
Carbon dioxide.
Irritant vapours or gases.

Condition

During combustion.
During combustion.
During combustion.

5.3. Advice for fire-fighters

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

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

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

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Collect as much of the spilled material as possible. Place in a closed container approved for transportation by appropriate authorities. Clean up residue. 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
Calcium hydroxide	1305-62-0	UK HSC	TWA(respirable fraction):1 mg/m ³ ;TWA:5 mg/m ³ ;STEL(respirable fraction):4 mg/m ³	
Titanium dioxide	13463-67-7	UK HSC	TWA(Inhalable):10 mg/m ³ ;TWA(respirable):4 mg/m ³	
Silicon dioxide	68909-20-6	UK HSC	TWA(as inhalable dust):6	

mg/m³;TWA(as respirable
dust):2.4 mg/m³

UK HSC : UK Health and Safety Commission

TWA: Time-Weighted-Average

STEL: Short Term Exposure Limit

CEIL: Ceiling

Biological limit values

No biological limit values exist for any of the components listed in Section 3 of this safety information sheet.

8.2. Exposure controls

8.2.1. Engineering controls

Use in a well-ventilated area.

8.2.2. Personal protective equipment (PPE)

Eye/face protection

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

Safety glasses with side shields.

Applicable Norms/Standards

Use eye protection conforming to EN 166

Skin/hand protection

See Section 7.1 for additional information on skin protection.

Respiratory protection

None required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state

Solid.

Colour

Tooth

Specific Physical Form:

Paste

Odor

Slight Acrylic

pH

Not applicable.

Boiling point/boiling range

No data available.

Melting point

No data available.

Flammability (solid, gas)

Not classified

Explosive properties

Not classified

Oxidising properties

Not classified

Flash point

No flash point

Autoignition temperature

No data available.

Flammable Limits(LEL)

No data available.

Flammable Limits(UEL)

No data available.

Relative density

2 - 2.2 [Ref Std: WATER=1]

Water solubility

Nil

Viscosity

No data available.

Density

2 - 2.2 g/cm³

9.2. Other information**EU Volatile Organic Compounds***No data available.***Molecular weight***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

None known.

10.6 Hazardous decomposition products**Substance****Condition**

None known.

Refer to section 5.2 for hazardous decomposition products during combustion.

SECTION 11: Toxicological information

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

11.1 Information on Toxicological effects**Signs and Symptoms of Exposure**

Based on test data and/or information on the components, this material may produce the following health effects:

Inhalation

This product may have a characteristic odour; however, no adverse health effects are anticipated.

Skin contact

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

Eye contact

Severe eye irritation: Signs/symptoms may include significant redness, swelling, pain, tearing, cloudy appearance of

the cornea, and impaired vision.

Ingestion

May be harmful if swallowed.

Gastrointestinal irritation: Signs/symptoms may include abdominal pain, stomach upset, nausea, vomiting and diarrhoea.

Additional Health Effects:

Carcinogenicity:

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

Contains a chemical or chemicals which can cause cancer.

Toxicological Data

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

Acute Toxicity

Name	Route	Species	Value
Overall product	Dermal		No data available; calculated ATE >5,000 mg/kg
Overall product	Ingestion		No data available; calculated ATE 2,000 - 5,000 mg/kg
Silane treated glass powder	Dermal		LD50 estimated to be > 5,000 mg/kg
Silane treated glass powder	Ingestion		LD50 estimated to be 2,000 - 5,000 mg/kg
Substituted dimethacrylate	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Substituted dimethacrylate	Ingestion	Rat	LD50 > 17,600 mg/kg
Aliphatic dimethacrylate	Dermal	Professional judgement	LD50 estimated to be 2,000 - 5,000 mg/kg
Aliphatic dimethacrylate	Ingestion	similar compounds	LD50 2000-5000 mg/kg
Salt of substituted barbituric acid	Dermal	Professional judgement	LD50 estimated to be 2,000 - 5,000 mg/kg
Salt of substituted barbituric 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
Calcium hydroxide	Dermal	Rabbit	LD50 > 2,500 mg/kg
Calcium hydroxide	Ingestion	Rat	LD50 7,340 mg/kg
Sulfinate	Dermal	Professional judgement	LD50 estimated to be 2,000 - 5,000 mg/kg
Sulfinate	Ingestion	Rat	LD50 3,200 mg/kg
Methacrylated amine	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Methacrylated amine	Ingestion	Rat	LD50 > 1,600 mg/kg
Titanium dioxide	Dermal	Rabbit	LD50 > 10,000 mg/kg
Titanium dioxide	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 6.82 mg/l
Titanium dioxide	Ingestion	Rat	LD50 > 10,000 mg/kg
Methacrylated amine	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Methacrylated amine	Ingestion	Rat	LD50 > 400 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Silane treated glass powder	Professional judgement	No significant irritation
Substituted dimethacrylate	Rabbit	No significant irritation
Silane treated silica	Rabbit	No significant irritation
Calcium hydroxide	Human	Corrosive
Titanium dioxide	Rabbit	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
Silane treated glass powder	Professional judgement	No significant irritation
Substituted dimethacrylate	Rabbit	Mild irritant
Silane treated silica	Rabbit	No significant irritation
Calcium hydroxide	Rabbit	Corrosive
Titanium dioxide	Rabbit	No significant irritation

Skin Sensitisation

Name	Species	Value
Substituted dimethacrylate	Guinea pig	Not classified
Salt of substituted barbituric acid	Mouse	Not classified
Silane treated silica	Human and animal	Not classified
Methacrylated amine	Professional judgement	Sensitising
Titanium dioxide	Human and animal	Not classified
Methacrylated amine	Professional judgement	Sensitising

Respiratory Sensitisation

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

Germ Cell Mutagenicity

Name	Route	Value
Substituted dimethacrylate	In Vitro	Not mutagenic
Salt of substituted barbituric acid	In Vitro	Not mutagenic
Silane treated silica	In Vitro	Not mutagenic
Titanium dioxide	In Vitro	Not mutagenic
Titanium dioxide	In vivo	Not mutagenic

Carcinogenicity

Name	Route	Species	Value
Silane treated silica	Not specified.	Mouse	Some positive data exist, but the data are not sufficient for classification
Titanium dioxide	Ingestion	Multiple animal species	Not carcinogenic
Titanium dioxide	Inhalation	Rat	Carcinogenic.

Reproductive Toxicity**Reproductive and/or Developmental Effects**

Name	Route	Value	Species	Test result	Exposure Duration
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

Target Organ(s)**Specific Target Organ Toxicity - single exposure**

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Salt of substituted barbituric acid	Ingestion	nervous system	Not classified	Rat	NOAEL 2,000 mg/kg	
Calcium hydroxide	Inhalation	respiratory irritation	Some positive data exist, but the data are not sufficient for classification	Human	LOAEL 2.5 mg/m3	20 minutes

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Silane treated silica	Inhalation	respiratory system silicosis	Not classified	Human	NOAEL Not available	occupational exposure
Titanium dioxide	Inhalation	respiratory system	Some positive data exist, but the data are not sufficient for classification	Rat	LOAEL 0.01 mg/l	2 years
Titanium dioxide	Inhalation	pulmonary fibrosis	Not classified	Human	NOAEL Not available	occupational exposure

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
Silane treated glass powder	None		Data not available or insufficient for classification			
Substituted dimethacrylate	27689-12-9	Green algae	Experimental	72 hours	EC50	>100 mg/l
Substituted dimethacrylate	27689-12-9	Water flea	Experimental	48 hours	EC50	>100 mg/l
Substituted dimethacrylate	27689-12-9	Green algae	Experimental	72 hours	NOEC	>100 mg/l
Salt of substituted barbituric acid	945012-02-2		Data not available or insufficient for classification			
Aliphatic dimethacrylate	72829-09-5	Green Algae	Experimental	72 hours	EC50	17 µg/l
Aliphatic dimethacrylate	72829-09-5	Water flea	Experimental	48 hours	EC50	>100 mg/l
Aliphatic dimethacrylate	72829-09-5	Green Algae	Experimental	72 hours	Effect Concentration 10%	6.4 µg/l
Silane treated silica	68909-20-6	Algae	Estimated	72 hours	EC50	>100 mg/l
Sulfinate	824-79-3	Fathead minnow	Estimated	96 hours	LC50	>400 mg/l
Sulfinate	824-79-3	Green Algae	Estimated	96 hours	EC50	230 mg/l
Sulfinate	824-79-3	Water flea	Estimated	48 hours	EC50	>400 mg/l
Sulfinate	824-79-3	Green Algae	Estimated	96 hours	NOEC	31 mg/l
Calcium hydroxide	1305-62-0	Fathead minnow	Estimated	96 hours	LC50	4,630 mg/l
Calcium hydroxide	1305-62-0	Green Algae	Estimated	72 hours	EC50	>4,000 mg/l

Calcium hydroxide	1305-62-0	Water flea	Estimated	48 hours	EC50	2,400 mg/l
Methacrylated amine	93962-71-1		Data not available or insufficient for classification			
Methacrylated amine	93962-70-0		Data not available or insufficient for classification			
Titanium dioxide	13463-67-7	Diatom	Experimental	72 hours	EC50	>10,000 mg/l
Titanium dioxide	13463-67-7	Fathead minnow	Experimental	96 hours	LC50	>100 mg/l
Titanium dioxide	13463-67-7	Water flea	Experimental	48 hours	EC50	>100 mg/l
Titanium dioxide	13463-67-7	Diatom	Experimental	72 hours	NOEC	5,600 mg/l

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Silane treated glass powder	None	Data not available or insufficient			N/A	
Substituted dimethacrylate	27689-12-9	Experimental Biodegradation	28 days	CO2 evolution	7-12 % weight	OECD 301B - Modified sturm or CO2
Salt of substituted barbituric acid	945012-02-2	Data not available or insufficient			N/A	
Aliphatic dimethacrylate	72829-09-5	Experimental Biodegradation	28 days	CO2 evolution	97.3 %CO2 evolution/THC O2 evolution	OECD 301B - Modified sturm or CO2
Silane treated silica	68909-20-6	Data not available or insufficient			N/A	
Sulfinate	824-79-3	Experimental Biodegradation	28 days	BOD	91 % BOD/ThBOD	OECD 301C - MITI test (I)
Calcium hydroxide	1305-62-0	Data not available or insufficient			N/A	
Methacrylated amine	93962-71-1	Estimated Biodegradation	28 days	BOD	55 % weight	OECD 301C - MITI test (I)
Methacrylated amine	93962-70-0	Estimated Biodegradation	28 days	BOD	77 % weight	OECD 301F - Manometric respirometry
Titanium dioxide	13463-67-7	Data not available or insufficient			N/A	

12.3 : Bioaccumulative potential

Material	Cas No.	Test type	Duration	Study Type	Test result	Protocol
Silane treated glass powder	None	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Substituted dimethacrylate	27689-12-9	Estimated Bioconcentration		Log Kow	7.61	Estimated: Octanol-water partition coefficient
Salt of substituted barbituric acid	945012-02-2	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Aliphatic dimethacrylate	72829-09-5	Estimated Bioconcentration		Bioaccumulation factor	6.6	Estimated: Bioconcentration factor
Silane treated silica	68909-20-6	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Sulfinate	824-79-3	Estimated Bioconcentration		Bioaccumulation factor	3.9	Estimated: Bioconcentration factor
Calcium hydroxide	1305-62-0	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Methacrylated amine	93962-71-1	Estimated Bioconcentration		Bioaccumulation factor	3.4	Estimated: Bioconcentration factor

Methacrylated amine	93962-70-0	Estimated Bioconcentration		Bioaccumulation factor	2.4	Estimated: Bioconcentration factor
Titanium dioxide	13463-67-7	Experimental BCF-Carp	42 days	Bioaccumulation factor	9.6	Other methods

12.4. Mobility in soil

Please contact manufacturer for more details

12.5. Results of the PBT and vPvB assessment

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

12.6. Other adverse effects

No information available.

SECTION 13: Disposal considerations**13.1 Waste treatment methods**

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

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

EU waste code (product as sold)

180106* Chemicals consisting of or containing dangerous substances.

SECTION 14: Transportation information

ADR: UN3077; Environmentally Hazardous Substance, Solid, N.O.S (Aliphatic dimethacrylate); 9; III; (-); M7.

IATA: UN3077; Environmentally Hazardous Substance, Solid, N.O.S (Aliphatic dimethacrylate); 9; III.

IMDG: UN3077; Environmentally Hazardous Substance, Solid, N.O.S (Aliphatic dimethacrylate); 9; III; EMS: FA, SF; Marine Pollutant: Aliphatic dimethacrylate. (ENG)

Exemption: For vessels containing a net quantity of 5 l or a net mass of 5 kg or less per single or inner packaging, special provision 375 (ADR), exemption per 2.10.2.7 (IMDG) or special provision A197 (IATA) may be applied, if applicable

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**

H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
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.
H413	May cause long lasting harmful effects to aquatic life.

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