



Safety Data Sheet

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Document group: 28-3754-0
Revision date: 15/03/2012
Transportation version number:

Version number: 1.00
Supersedes date: Initial issue.

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

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

1.1. Product identifier

3M™ ESPE™ RelyX™ Unicem 2 Automix Refill

Product identification numbers

70-2011-4030-1 70-2011-4031-9 70-2011-4032-7

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

Dental Product

1.3. Details of the supplier of the substance or mixture

Address: 3M United Kingdom PLC, 3M Centre, Cain Road, Bracknell, Berkshire, RG12 8HT.

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. A Safety Data Sheet for each of these components is included. Please do not separate the component Safety Data Sheets from this cover page. The document numbers of the MSDSs for components of this product are:

28-1333-5, 28-1380-6

TRANSPORTATION INFORMATION

KIT LABEL

2.2. Label elements

Dangerous substances(67/548/EEC)/preparations(1999/45/EC) directive

Symbols

Xn Harmful.

Contains:

Consult the component labels for disclosable ingredients.

Risk phrases

R42/43 May cause sensitisation by inhalation and skin contact.

Safety phrases

S23A Do not breathe vapour.
S24 Avoid contact with skin.
S37 Wear suitable gloves.
S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

Notes on labelling

For composition information see Part A (28-1380-6) and Part B (28-1333-5).

Revision information:

No revision information is available.



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Document group:	28-1333-5	Version number:	1.00
Revision date:	15/03/2012	Supersedes date:	Initial issue.
Transportation version number:	1.00 (15/03/2012)		

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

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

1.1. Product identifier

3M™ ESPE™ RelyX™ UNICEM 2 AUTOMIX Catalyst

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

Identified uses

Dental Product

1.3. Details of the supplier of the substance or mixture

Address: 3M United Kingdom PLC, 3M Centre, Cain Road, Bracknell, Berkshire, RG12 8HT.

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

Dangerous substances(67/548/EEC)/preparations(1999/45/EC) directive

Indication of danger

Irritant.

Sensitising

2.2. Label elements

Dangerous substances(67/548/EEC)/preparations(1999/45/EC) directive

Symbols

Xi Irritant.

Contains:

1,12-Dodecanediyl bismethacrylate

Risk phrases

R43 May cause sensitisation by skin contact.

Safety phrases

S24 Avoid contact with skin.
S37 Wear suitable gloves.

This product is exempt from labelling per Directive 1999/45/EC as it is defined as a medical device according to Directive 93/42/EEC and is invasive or comes into contact with the human body.

2.3. Other hazards

None known.

SECTION 3: Composition/information on ingredients

Ingredient	CAS Nbr	EU Inventory	% by Wt	Classification
Silane treated glass powder	None		55 - 65	
(1-Methylethylidene)bis(4,1-phenyleneoxy-3,1-propanediyl) bismethacrylate	27689-12-9	EINECS 248-607-1	20 - 30	
1-benzyl-5-phenyl-barbic-acid, calcium salt	None		< 5	
1,12-Dodecanediyl bismethacrylate	72829-09-5	EINECS 276-900-4	< 5	Xi:R36-37-38; R43 (Vendor) Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335 (Vendor)
Sodium toluene-4-sulphinate	824-79-3	EINECS 212-538-5	< 5	
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	68909-20-6	EINECS 272-697-1	< 5	
Calcium Hydroxide	1305-62-0	EINECS 215-137-3	< 2	Xi:R41 (Vendor) Eye Dam. 1, H318 (Vendor)
Titanium dioxide	13463-67-7	EINECS 236-675-5	< 0.5	

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

Please refer to section 15 for the any applicable Notas that have been applied to the above components

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

SECTION 4: First aid measures
4.1. Description of first aid measures
Eye contact

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

Inhalation

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

If swallowed

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

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

See Section 11.1 Information on toxicological effects

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

Not applicable

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

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

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

No unusual fire or explosion hazards are anticipated.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Evacuate area. Ventilate the area with fresh air.

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. Dispose of collected material as soon as possible.

6.4. Reference to other sections

Refer to Section 8 and Section 13 for more information

SECTION 7: Handling and storage

7.1. Precautions for safe handling

A no-touch technique is recommended. If skin contact occurs, wash skin with soap and water. Acrylates may penetrate commonly-used gloves. If product contacts glove, remove and discard glove, wash hands immediately with soap and water and then re-glove. Avoid breathing dust/fume/gas/mist/vapours/spray. Do not get in eyes, on skin, or on clothing. Do not eat, drink or smoke when using this product. Wash thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse.

7.2. Conditions for safe storage including any incompatibilities

Store away from heat. Protect from sunlight.

7.3. Specific end use(s)

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

SECTION 8: Exposure controls/personal protection**8.1 Control parameters****Occupational exposure limits**

Ingredient	CAS Nbr	Agency	Limit type	Additional comments
Calcium Hydroxide	1305-62-0	Health and Safety Comm. (UK)	TWA:5 mg/m ³	
Titanium dioxide	13463-67-7	Health and Safety Comm. (UK)	TWA(Inhalable):10 mg/m ³ ;TWA(respirable):4 mg/m ³	

Health and Safety Comm. (UK) : UK Health and Safety Commission

TWA: Time-Weighted-Average

STEL: Short Term Exposure Limit

ppm: parts per million

mg/m³: milligrams per cubic metre

CEIL: Ceiling

8.2. Exposure controls**8.2.1. Engineering controls**

Use general dilution ventilation and/or local exhaust ventilation to control airborne exposures to below relevant Exposure Limits and/or control dust/fume/gas/mist/vapours/spray. If ventilation is not adequate, use respiratory protection equipment.

8.2.2. Personal protective equipment (PPE)**Eye/face protection**

The following eye protection(s) are recommended: Safety glasses with side shields.

Skin/hand protection

Skin protection is not required.

Respiratory protection

Under normal use conditions, airborne exposures are not expected to be significant enough to require respiratory protection.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state	Solid.
Specific Physical Form:	Paste
Appearance/Odour	tooth-coloured pastes with slight acrylic odour
pH	<i>Not applicable.</i>
Boiling point/boiling range	<i>No data available.</i>
Melting point	<i>No data available.</i>
Flammability (solid, gas)	Not classified

Explosive properties	Not classified
Oxidising properties	Not classified
Flash point	No flash point
Autoignition temperature	<i>No data available.</i>
Flammable Limits(LEL)	<i>No data available.</i>
Flammable Limits(UEL)	<i>No data available.</i>
Vapour pressure	<i>No data available.</i>
Relative density	2 - 2.2 [Ref Std: WATER=1]
Water solubility	Nil
Partition coefficient: n-octanol/water	<i>No data available.</i>
Evaporation rate	<i>No data available.</i>
Vapour density	<i>No data available.</i>
Viscosity	<i>No data available.</i>
Density	2 - 2.2 g/cm ³

9.2. Other information

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

None known.

Condition

SECTION 11: Toxicological information

The information below may not be consistent with the material classification in Section 2 if specific ingredient classifications are mandated by a competent authority. In addition, toxicological data on ingredients may not be reflected in the material classification and/or the signs and symptoms of exposure, because an ingredient may be present below the threshold for labelling, an ingredient may not be available for exposure, or the data may not be relevant to the material as a whole.

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:

Eye contact

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

Skin contact

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

Inhalation

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

Ingestion

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

Toxicological Data

Acute Toxicity

Name	Route	Species	Value	UN GHS Classification
Overall product	Ingestion		No test data available; calculated ATE >5,000 mg/kg	Not classified (72.33% unknown)
(1-Methylethylidene)bis(4,1-phenyleneoxy-3,1-propanediyl) bismethacrylate	Ingestion	Rat	LD50 > 17,600 mg/kg	Not classified
1,12-Dodecanediyl bismethacrylate			No data available	
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Dermal	Rabbit	LD50 > 5,000 mg/kg	Not classified
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 0.691 mg/l	Category 5
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Ingestion	Rat	LD50 > 5,110 mg/kg	Not classified
Sodium toluene-4-sulphonate			No data available	
Calcium Hydroxide	Ingestion	Rat	LD50 7,340 mg/kg	Not classified
Titanium dioxide	Dermal	Rabbit	LD50 > 10,000 mg/kg	Not classified
Titanium dioxide	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 7 mg/l	Category 5
Titanium dioxide	Ingestion	Rat	LD50 > 10,000 mg/kg	Not classified

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value	UN GHS Classification
Overall product		No test data available; calculated to cause no significant irritation	Not classified
(1-Methylethylidene)bis(4,1-phenyleneoxy-3,1-propanediyl) bismethacrylate		No significant irritation	Not classified
1,12-Dodecanediyl bismethacrylate		No data available	
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Rabbit	No significant irritation	Not classified
Sodium toluene-4-sulphonate		No data available	

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Calcium Hydroxide		No data available	
Titanium dioxide		No significant irritation	Not classified

Serious Eye Damage/Irritation

Name	Species	Value	UN GHS Classification
Overall product		No test data available; calculated to cause no significant irritation	Not classified
(1-Methylethylidene)bis(4,1-phenyleneoxy-3,1-propanediyl) bismethacrylate		Mild irritant	Not classified
1,12-Dodecanediyl bismethacrylate		No data available	
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Rabbit	No significant irritation	Not classified
Sodium toluene-4-sulphinate		No data available	
Calcium Hydroxide		No data available	
Titanium dioxide		Mild irritant	Not classified

Skin Sensitisation

Name	Species	Value	UN GHS Classification
Overall product		No test data available.	Category 1 based on component data
(1-Methylethylidene)bis(4,1-phenyleneoxy-3,1-propanediyl) bismethacrylate		Not sensitizing	Not classified
1,12-Dodecanediyl bismethacrylate		No data available	
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Human and animal	Not sensitizing	Not classified
Sodium toluene-4-sulphinate		No data available	
Calcium Hydroxide		No data available	
Titanium dioxide		Not sensitizing	Not classified

Respiratory Sensitisation

Name	Species	Value	UN GHS Classification
Overall product		No test data available.	Not classified based on component data
(1-Methylethylidene)bis(4,1-phenyleneoxy-3,1-propanediyl) bismethacrylate		No data available	
1,12-Dodecanediyl bismethacrylate		No data available	
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica		No data available	
Sodium toluene-4-sulphinate		No data available	
Calcium Hydroxide		No data available	
Titanium dioxide		No data available	

Germ Cell Mutagenicity

Name	Route	Value	UN GHS Classification
Overall product		No data available	Overall Germ Cell Mutagenicity classification Not classified
Overall product		No test data available.	
(1-Methylethylidene)bis(4,1-phenyleneoxy-3,1-propanediyl) bismethacrylate	In Vitro	Not mutagenic	Not classified
1,12-Dodecanediyl bismethacrylate		No data available	
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	In Vitro	Not mutagenic	Not classified
Sodium toluene-4-sulphinate		No data available	
Calcium Hydroxide		No data available	

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Titanium dioxide	In Vitro	Not mutagenic	Not classified
Titanium dioxide	Ingestion	Not mutagenic	Not classified

Carcinogenicity

Name	Route	Species	Value	UN GHS Classification
Overall product			No test data available.	Not classified based on component data
(1-Methylethylidene)bis(4,1-phenyleneoxy-3,1-propanediyl) bismethacrylate			No data available	
1,12-Dodecanediyl bismethacrylate			No data available	
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Not specified.	Mouse	Some positive data exist, but the data are not sufficient for classification	Not classified
Sodium toluene-4-sulphinate			No data available	
Calcium Hydroxide			No data available	
Titanium dioxide	Ingestion		Not carcinogenic	Not classified
Titanium dioxide	Inhalation		Some positive data exist, but the data are not sufficient for classification	Not classified

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

Name	Route	Value	Species	Test result	Exposure Duration	UN GHS Classification
Overall product		No test data available.				Not classified based on component data
(1-Methylethylidene)bis(4,1-phenyleneoxy-3,1-propanediyl) bismethacrylate		No data available				
1,12-Dodecanediyl bismethacrylate		No data available				
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Ingestion	Not toxic to female reproduction	Rat	NOAEL 509 mg/kg/day	1 generation	
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Ingestion	Not toxic to male reproduction	Rat	NOAEL 497 mg/kg/day	1 generation	
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Ingestion	Not toxic to development	Rat	NOAEL 1,350 mg/kg/day	during organogenesis	
Sodium toluene-4-sulphinate		No data available				
Calcium Hydroxide		No data available				
Titanium dioxide		No data available				

Target Organ(s)

Specific Target Organ Toxicity - single exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration	UN GHS Classification
(1-Methylethylidene)bis(4,1-phenyleneoxy-3,1-propanediyl) bismethacrylate			No data available				
1,12-Dodecanediyl bismethacrylate			No data available				
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica			No data available				
Sodium toluene-4-sulphinate			No data available				
Calcium Hydroxide			No data available				
Titanium dioxide	Inhalation	respiratory irritation	Some positive data exist, but the data are not sufficient for classification		Irritation Positive		Not classified

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration	UN GHS Classification
Overall product			No test data available.				Not classified based on component data
(1-Methylethylidene)bis(4,1-phenyleneoxy-3,1-propanediyl) bismethacrylate			No data available				
1,12-Dodecanediyl bismethacrylate			No data available				
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Inhalation	respiratory system silicosis	All data are negative	Human	NOAEL Not available	occupational exposure	Not classified
Sodium toluene-4-sulphinate			No data available				

Calcium Hydroxide			No data available				
Titanium dioxide	Inhalation	respiratory system	Some positive data exist, but the data are not sufficient for classification		NOEL 10 mg/m3		Not classified
Titanium dioxide	Inhalation	pulmonary fibrosis	All data are negative		NOAEL N/A		Not classified

Aspiration Hazard

Name	Value	UN GHS Classification
Overall product	No test data available.	Not classified based on component and/or viscosity data
(1-Methylethylidene)bis(4,1-phenyleneoxy-3,1-propanediyl) bismethacrylate	Not an aspiration hazard	Not classified
1,12-Dodecanediyl bismethacrylate	Not an aspiration hazard	Not classified
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Not an aspiration hazard	Not classified
Sodium toluene-4-sulphonate	Not an aspiration hazard	Not classified
Calcium Hydroxide	Not an aspiration hazard	Not classified
Titanium dioxide	Not an aspiration hazard	Not classified

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

SECTION 12: Ecological information

The information below may not be consistent with the material classification in Section 2 if specific ingredient classifications are mandated by a competent authority. Additional information leading to material classification in Section 2 is available upon request. In addition, environmental fate and effects data on ingredients may not be reflected in this section because an ingredient is present below the threshold for labelling, an ingredient is not expected to be available for exposure, or the data is considered not relevant to the material as a whole.

12.1. Toxicity

Acute aquatic hazard:

Not acutely toxic to aquatic life by GHS criteria.

Chronic aquatic hazard:

Not chronically toxic to aquatic life by GHS criteria.

No product test data available.

No component test data available.

12.2. Persistence and degradability

No test data available.

12.3 : Bioaccumulative potential

No test data available.

12.4. Mobility in soil

Please contact manufacturer for more details

12.5. Results of the PBT and vPvB assessment

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

12.6. Other adverse effects

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

Empty drums/barrels/containers used for transporting and handling hazardous chemicals (chemical substances/mixtures/preparations classified as hazardous as per applicable regulations) shall be considered, stored, treated & disposed of as hazardous wastes unless otherwise defined by applicable waste regulations. Consult with the respective regulating authorities to determine the available treatment and disposal facilities. Incinerate in a permitted waste incineration facility. Proper destruction may require the use of additional fuel during incineration processes.

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

EU waste code (product as sold)

180106* Chemicals consisting of or containing dangerous substances.

SECTION 14: Transportation information

ADR: Not restricted for transport.

IMDG: Not restricted for transport.

IATA: Not restricted for transport.

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****Carcinogenicity****Ingredient**

Titanium dioxide

CAS Nbr

13463-67-7

ClassificationGrp. 2B: Possible human
carc.**Regulation**International Agency
for Research on Cancer**Global inventory status**

Contact 3M for more information.

15.2. Chemical Safety Assessment

Not applicable

SECTION 16: Other information**List of relevant H statements**

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.

List of relevant R-phrases

R36	Irritating to eyes.
R37	Irritating to respiratory system.
R38	Irritating to skin.
R41	Risk of serious damage to eyes.
R43	May cause sensitisation by skin contact.

Revision information:

No revision information is available.

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

3M United Kingdom MSDSs are available at www.3M.com/uk



Safety Data Sheet

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

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

1.1. Product identifier

3M™ ESPE™ RelyX™ UNICEM 2 AUTOMIX Base Paste

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

Identified uses

Dental Product

1.3. Details of the supplier of the substance or mixture

Address: 3M United Kingdom PLC, 3M Centre, Cain Road, Bracknell, Berkshire, RG12 8HT.

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

Dangerous substances(67/548/EEC)/preparations(1999/45/EC) directive

Indication of danger

Harmful.

Sensitising

2.2. Label elements

Dangerous substances(67/548/EEC)/preparations(1999/45/EC) directive

Symbols

Xn Harmful.

Contains:

2-Propenoic acid, 2-methyl-, 1,1'-[1-(hydroxymethyl)-1,2-ethanediyl] ester, reaction products with 2-hydroxy-1,3-

3M™ ESPE™ RelyX™ UNICEM 2 AUTOMIX Base Paste

propanediyl dimethacrylate and phosphorus oxide; Disodium peroxodisulphate; 2,2'-Ethylenedioxydiethyl dimethacrylate

Risk phrases

R42/43 May cause sensitisation by inhalation and skin contact.

Safety phrases

S23A Do not breathe vapour.
S24 Avoid contact with skin.
S37 Wear suitable gloves.
S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

Notes on labelling

This product is exempt from labelling per Directive 1999/45/EC as it is defined as a medical device according to Directive 93/42/EEC and is invasive or comes into contact with the human body.

R41 not applied due to negative ocular irritation study results.

2.3. Other hazards

None known.

SECTION 3: Composition/information on ingredients

Ingredient	CAS Nbr	EU Inventory	% by Wt	Classification
Silane treated glass powder	None		45 - 55	
2-Propenoic acid, 2-methyl-, 1,1'-[1-(hydroxymethyl)-1,2-ethanediyl] ester, reaction products with 2-hydroxy-1,3-propanediyl dimethacrylate and phosphorus oxide	1224866-76-5		20 - 30	Xi:R41; R43 (Self Classified) Eye Dam. 1, H318; Skin Sens. 1, H317 (Self Classified)
2,2'-Ethylenedioxydiethyl dimethacrylate	109-16-0	EINECS 203-652-6	10 - 20	R43 (Self Classified) Skin Sens. 1, H317 (Self Classified)
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	68909-20-6	EINECS 272-697-1	1 - 10	
Glass, oxide, chemicals	65997-17-3	EINECS 266-046-0	< 3	
Disodium peroxodisulphate	7775-27-1	EINECS 231-892-1	< 3	O:R8; Xn:R22; Xi:R36-37-38; R42-43 (Vendor) Ox. Sol. 3, H272; Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Resp. Sens. 1, H334; Skin Sens. 1, H317; STOT SE 3, H335 (Vendor)
Tert-butyl 3,5,5-trimethylperoxyhexanoate	13122-18-4	EINECS 236-050-7	< 0.5	O:R7; Xi:R38; N:R50/53; R43 (Vendor) Org. Perox. CD, H242; Skin Irrit. 2, H315; Skin Sens. 1, H317; Aquatic Acute 1, H400; M=1; Aquatic Chronic 1,

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

Please refer to section 15 for the any applicable Notas that have been applied to the above components

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

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye contact

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

Inhalation

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

If swallowed

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

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

See Section 11.1 Information on toxicological effects

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

Not applicable

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

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

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

No unusual fire or explosion hazards are anticipated.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Ventilate the area with fresh air. Refer to other sections of this SDS for information regarding physical and health hazards, respiratory protection, ventilation, and personal protective equipment.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Collect as much of the spilled material as possible. Clean up residue with detergent and water. Place in a closed container approved for transportation by appropriate authorities. Dispose of collected material as soon as possible.

6.4. Reference to other sections

Refer to Section 8 and Section 13 for more information

SECTION 7: Handling and storage**7.1. Precautions for safe handling**

Do not get in eyes, on skin, or on clothing. A no-touch technique is recommended. If skin contact occurs, wash skin with soap and water. Acrylates may penetrate commonly-used gloves. If product contacts glove, remove and discard glove, wash hands immediately with soap and water and then re-glove. Avoid breathing dust/fume/gas/mist/vapours/spray. Do not eat, drink or smoke when using this product. Wash thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse. Avoid release to the environment.

7.2. Conditions for safe storage including any incompatibilities

Store away from heat. Protect from sunlight.

7.3. Specific end use(s)

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

SECTION 8: Exposure controls/personal protection**8.1 Control parameters****Occupational exposure limits**

Ingredient	CAS Nbr	Agency	Limit type	Additional comments
Glass filaments	65997-17-3	Health and Safety Comm. (UK)	TWA(as fiber):5 mg/m3(1 fibers/ml)	
Glass, oxide, chemicals	65997-17-3	Manufacturer determined	TWA(as dust):10 mg/m3	

Health and Safety Comm. (UK) : UK Health and Safety Commission

TWA: Time-Weighted-Average

STEL: Short Term Exposure Limit

ppm: parts per million

mg/m³: milligrams per cubic metre

CEIL: Ceiling

8.2. Exposure controls**8.2.1. Engineering controls**

Use general dilution ventilation and/or local exhaust ventilation to control airborne exposures to below relevant Exposure Limits and/or control dust/fume/gas/mist/vapours/spray. If ventilation is not adequate, use respiratory protection equipment.

8.2.2. Personal protective equipment (PPE)**Eye/face protection**

The following eye protection(s) are recommended: Safety glasses with side shields.

Skin/hand protection

Select and use gloves and/or protective clothing to prevent skin contact based on the results of an exposure assessment. Consult with your glove and/or protective clothing manufacturer for selection of appropriate compatible materials.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state	Solid.
Specific Physical Form:	Paste
Appearance/Odour	tooth-coloured paste with slight acrylic odour
pH	<i>Not applicable.</i>
Boiling point/boiling range	<i>No data available.</i>
Melting point	<i>No data available.</i>
Flammability (solid, gas)	Not classified
Explosive properties	Not classified
Oxidising properties	Not classified
Flash point	No flash point
Autoignition temperature	<i>No data available.</i>
Flammable Limits(LEL)	<i>No data available.</i>
Flammable Limits(UEL)	<i>No data available.</i>
Vapour pressure	<i>No data available.</i>
Relative density	2 - 2.2 [Ref Std: WATER=1]
Water solubility	Negligible
Partition coefficient: n-octanol/water	<i>No data available.</i>
Evaporation rate	<i>No data available.</i>
Vapour density	<i>No data available.</i>
Viscosity	<i>No data available.</i>
Density	2 - 2.2 g/cm ³

9.2. Other information**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

None known.

Condition

SECTION 11: Toxicological information

The information below may not be consistent with the material classification in Section 2 if specific ingredient classifications are mandated by a competent authority. In addition, toxicological data on ingredients may not be reflected in the material classification and/or the signs and symptoms of exposure, because an ingredient may be present below the threshold for labelling, an ingredient may not be available for exposure, or the data may not be relevant to the material as a whole.

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:

Eye contact

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

Skin contact

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

Inhalation

Respiratory tract irritation: Signs/symptoms may include cough, sneezing, nasal discharge, headache, hoarseness, and nose and throat pain. Allergic respiratory reaction: Signs/symptoms may include difficulty breathing, wheezing, cough, and tightness of chest.

Ingestion

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

Toxicological Data

Acute Toxicity

Name	Route	Species	Value	UN GHS Classification
Overall product	Ingestion		No test data available; calculated ATE >5,000 mg/kg	Not classified (75.5% unknown)
2-Propenoic acid, 2-methyl-, 1,1'-[1-(hydroxymethyl)-1,2-ethanediyl] ester, reaction products with 2-hydroxy-1,3-propanediyl dimethacrylate and phosphorus oxide			No data available	
2,2'-Ethylenedioxydiethyl dimethacrylate	Ingestion	Rat	LD50 10,837 mg/kg	Not classified
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Dermal	Rabbit	LD50 > 5,000 mg/kg	Not classified

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Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 0.691 mg/l	Category 5
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Ingestion	Rat	LD50 > 5,110 mg/kg	Not classified
Glass, oxide, chemicals	Dermal		LD50 estimated to be > 5,000 mg/kg	Not classified
Glass, oxide, chemicals	Ingestion		LD50 estimated to be 2,000 - 5,000 mg/kg	Category 5
Disodium peroxodisulphate			No data available	
Tert-butyl 3,5,5-trimethylperoxyhexanoate			No data available	

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value	UN GHS Classification
Overall product		No test data available; calculated to be mild irritant	Category 3
2-Propenoic acid, 2-methyl-, 1,1'-[1-(hydroxymethyl)-1,2-ethanediyl] ester, reaction products with 2-hydroxy-1,3-propanediyl dimethacrylate and phosphorus oxide		No data available	
2,2'-Ethylenedioxydiethyl dimethacrylate		Mild irritant	Category 3
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Rabbit	No significant irritation	Not classified
Glass, oxide, chemicals		No data available	
Disodium peroxodisulphate		No data available	
Tert-butyl 3,5,5-trimethylperoxyhexanoate		No data available	

Serious Eye Damage/Irritation

Name	Species	Value	UN GHS Classification
Overall product		No significant irritation	Not classified
2-Propenoic acid, 2-methyl-, 1,1'-[1-(hydroxymethyl)-1,2-ethanediyl] ester, reaction products with 2-hydroxy-1,3-propanediyl dimethacrylate and phosphorus oxide		No data available	
2,2'-Ethylenedioxydiethyl dimethacrylate		Moderate irritant	Category 2B
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Rabbit	No significant irritation	Not classified
Glass, oxide, chemicals		No data available	
Disodium peroxodisulphate		No data available	
Tert-butyl 3,5,5-trimethylperoxyhexanoate		No data available	

Skin Sensitisation

Name	Species	Value	UN GHS Classification
Overall product		No test data available.	Category 1 based on component data
2-Propenoic acid, 2-methyl-, 1,1'-[1-(hydroxymethyl)-1,2-ethanediyl] ester, reaction products with 2-hydroxy-1,3-propanediyl dimethacrylate and phosphorus oxide		No data available	
2,2'-Ethylenedioxydiethyl dimethacrylate		Sensitising	Category 1
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with	Human and animal	Not sensitizing	Not classified

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silica			
Glass, oxide, chemicals		No data available	
Disodium peroxodisulphate		No data available	
Tert-butyl 3,5,5-trimethylperoxyhexanoate		No data available	

Respiratory Sensitisation

Name	Species	Value	UN GHS Classification
Overall product		No test data available.	Category 1
2-Propenoic acid, 2-methyl-, 1,1'-[1-(hydroxymethyl)-1,2-ethanediyl] ester, reaction products with 2-hydroxy-1,3-propanediyl dimethacrylate and phosphorus oxide		No data available	
2,2'-Ethylenedioxydiethyl dimethacrylate		No data available	
Silanameine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica		No data available	
Glass, oxide, chemicals		No data available	
Disodium peroxodisulphate		No data available	
Tert-butyl 3,5,5-trimethylperoxyhexanoate		No data available	

Germ Cell Mutagenicity

Name	Route	Value	UN GHS Classification
Overall product		No data available	Overall Germ Cell Mutagenicity classification Not classified
Overall product		No test data available.	
2-Propenoic acid, 2-methyl-, 1,1'-[1-(hydroxymethyl)-1,2-ethanediyl] ester, reaction products with 2-hydroxy-1,3-propanediyl dimethacrylate and phosphorus oxide		No data available	
2,2'-Ethylenedioxydiethyl dimethacrylate	In Vitro	Some positive data exist, but the data are not sufficient for classification	Not classified
Silanameine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	In Vitro	Not mutagenic	Not classified
Glass, oxide, chemicals	In Vitro	Some positive data exist, but the data are not sufficient for classification	Not classified
Disodium peroxodisulphate		No data available	
Tert-butyl 3,5,5-trimethylperoxyhexanoate		No data available	

Carcinogenicity

Name	Route	Species	Value	UN GHS Classification
Overall product			No test data available.	Not classified based on component data
2-Propenoic acid, 2-methyl-, 1,1'-[1-(hydroxymethyl)-1,2-ethanediyl] ester, reaction products with 2-hydroxy-1,3-propanediyl dimethacrylate and phosphorus oxide			No data available	
2,2'-Ethylenedioxydiethyl dimethacrylate	Dermal		Not carcinogenic	Not classified
Silanameine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Not specified.	Mouse	Some positive data exist, but the data are not sufficient for classification	Not classified
Glass, oxide, chemicals	Inhalation		Carcinogenic.	Category 2
Disodium peroxodisulphate			No data available	

Tert-butyl 3,5,5-trimethylperoxyhexanoate			No data available	
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Reproductive Toxicity**Reproductive and/or Developmental Effects**

Name	Route	Value	Species	Test result	Exposure Duration	UN GHS Classification
Overall product		No test data available.				Not classified based on component data
2-Propenoic acid, 2-methyl-, 1,1'-[1-(hydroxymethyl)-1,2-ethanediyl] ester, reaction products with 2-hydroxy-1,3-propanediyl dimethacrylate and phosphorus oxide		No data available				
2,2'-Ethylenedioxydiethyl dimethacrylate	Ingestion	Not toxic to reproduction and/or development		NOAEL 1 mg/kg/day		
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Ingestion	Not toxic to female reproduction	Rat	NOAEL 509 mg/kg/day	1 generation	
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Ingestion	Not toxic to male reproduction	Rat	NOAEL 497 mg/kg/day	1 generation	
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Ingestion	Not toxic to development	Rat	NOAEL 1,350 mg/kg/day	during organogenesis	
Glass, oxide, chemicals		No data available				
Disodium peroxodisulphate		No data available				
Tert-butyl 3,5,5-trimethylperoxyhexanoate		No data available				

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

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration	UN GHS Classification
2-Propenoic acid, 2-methyl-, 1,1'-[1-(hydroxymethyl)-1,2-ethanediyl] ester, reaction products with			No data available				

2-hydroxy-1,3-propanediyl dimethacrylate and phosphorus oxide							
2,2'-Ethylenedioxydiethyl dimethacrylate	Dermal	blood	All data are negative		NOAEL N/A		Not classified
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica			No data available				
Glass, oxide, chemicals	Inhalation	respiratory irritation	Some positive data exist, but the data are not sufficient for classification		Irritation Positive		Not classified
Disodium peroxodisulphate			No data available				
Tert-butyl 3,5,5-trimethylperoxyhexanoate			No data available				

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration	UN GHS Classification
Overall product			No test data available.				Not classified based on component data
2-Propenoic acid, 2-methyl-, 1,1'-[1-(hydroxymethyl)-1,2-ethanediyl] ester, reaction products with 2-hydroxy-1,3-propanediyl dimethacrylate and phosphorus oxide			No data available				
2,2'-Ethylenedioxydiethyl dimethacrylate	Dermal	kidney and/or bladder	Some positive data exist, but the data are not sufficient for classification		NOAEL N/A		Not classified
Silanamine, 1,1,1-	Inhalation	respiratory system	All data are negative	Human	NOAEL Not	occupational exposure	Not classified

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trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica		silicosis			available		
Glass, oxide, chemicals	Inhalation	respiratory system	Some positive data exist, but the data are not sufficient for classification		NOEL N/A		Not classified
Disodium peroxodisulphate			No data available				
Tert-butyl 3,5,5-trimethylperoxyhexanoate			No data available				

Aspiration Hazard

Name	Value	UN GHS Classification
Overall product	No test data available.	Not classified based on component and/or viscosity data
2-Propenoic acid, 2-methyl-, 1,1'-[1-(hydroxymethyl)-1,2-ethanediyl] ester, reaction products with 2-hydroxy-1,3-propanediyl dimethacrylate and phosphorus oxide	Not an aspiration hazard	Not classified
2,2'-Ethylenedioxydiethyl dimethacrylate	Not an aspiration hazard	Not classified
Silnanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Not an aspiration hazard	Not classified
Glass, oxide, chemicals	Not an aspiration hazard	Not classified
Disodium peroxodisulphate	Not an aspiration hazard	Not classified
Tert-butyl 3,5,5-trimethylperoxyhexanoate	Not an aspiration hazard	Not classified

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

SECTION 12: Ecological information

The information below may not be consistent with the material classification in Section 2 if specific ingredient classifications are mandated by a competent authority. Additional information leading to material classification in Section 2 is available upon request. In addition, environmental fate and effects data on ingredients may not be reflected in this section because an ingredient is present below the threshold for labelling, an ingredient is not expected to be available for exposure, or the data is considered not relevant to the material as a whole.

12.1. Toxicity**Acute aquatic hazard:**

GHS Acute 3: Harmful to aquatic life.

Chronic aquatic hazard:

Not chronically toxic to aquatic life by GHS criteria.

No product test data available.

No component test data available.

12.2. Persistence and degradability

No test data available.

12.3 : Bioaccumulative potential

No test data available.

12.4. Mobility in soil

Please contact manufacturer for more details

12.5. Results of the PBT and vPvB assessment

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

12.6. Other adverse effects

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

Incinerate in a permitted waste incineration facility. Proper destruction may require the use of additional fuel during incineration processes.

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

EU waste code (product as sold)

180106* Chemicals consisting of or containing dangerous substances.

SECTION 14: Transportation information

ADR: Not restricted for transport.

IATA: Not restricted for transport.

IMDG: Not restricted for transport.

SECTION 15: Regulatory information

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

Global inventory status

Contact 3M for more information.

15.2. Chemical Safety Assessment

Not applicable

SECTION 16: Other information

List of relevant H statements

H242	Heating may cause a fire.
H272	May intensify fire; oxidizer.
H302	Harmful if swallowed.
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.

List of relevant R-phrases

R22	Harmful if swallowed.
R36	Irritating to eyes.
R37	Irritating to respiratory system.
R38	Irritating to skin.
R41	Risk of serious damage to eyes.
R42	May cause sensitisation by inhalation.
R43	May cause sensitisation by skin contact.
R50/53	Very toxic to aquatic organisms. May cause long-term adverse effects in the aquatic environment.
R7	May cause fire.
R8	Contact with combustible material may cause fire.

Revision information:

No revision information is available.

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

3M United Kingdom MSDSs are available at www.3M.com/uk