



Safety Data Sheet

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Document group:	16-2592-0	Version number:	3.00
Revision date:	05/02/2018	Supersedes date:	14/03/2011
Transportation version number: 1.00 (14/03/2011)			

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 Ketac Cem Radiopaque Permanent Glass Ionomer Luting Cement

Product Identification Numbers

70-2011-0339-0 70-2011-0342-4

7000054677 7000054680

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

Identified uses

Dental Product

Restrictions on Use

For use only by dental professionals

1.3. Details of the supplier of the safety data sheet

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

Telephone: +44 (0)1344 858 000

E Mail: tox.uk@mmm.com

Website: www.3M.com/uk

1.4. Emergency telephone number

+44 (0)1344 858 000

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:

26-9894-2, 16-2590-4

TRANSPORTATION INFORMATION

70-2011-0339-0, 70-2011-0342-4

3M ESPE Ketac Cem Radiopaque Permanent Glass Ionomer Luting Cement

Not hazardous for transportation

KIT LABEL

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

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) |

Pictograms



HAZARD STATEMENTS:

H319 Causes serious eye irritation.

PRECAUTIONARY STATEMENTS

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.

Revision information:

Kit: Component document group number(s) information was modified.
Company Telephone information was added.
Section 1: Product identification numbers information was modified.
Section 01: SAP Material Numbers information was added.
Section 1: Restrictions on use information information was added.
Section 2: Additional label requirements phrase information was deleted.
Section 2: H phrase reference information was added.
Label: CLP Classification information was added.
Section 02: Label Elements: CLP Medical Device information was added.
Label: CLP Precautionary - Response information was added.
Label: Graphic information was added.
Label: Signal Word information was added.

Section 15: Symbol information information was deleted.



Safety Data Sheet

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Document group:	16-2590-4	Version number:	4.01
Revision date:	05/02/2018	Supersedes date:	31/01/2018
Transportation version number: 1.00 (03/03/2011) 1.00 (03/03/2011)			

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

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

1.1. Product identifier

3M ESPE Ketac Cem Radiopaque Powder

Product Identification Numbers

70-2011-0340-8

7000054678

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

Identified uses

Dental Product

Restrictions on Use

For use by dental professionals only.

1.3. Details of the supplier of the safety data sheet

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

Telephone: +44 (0)1344 858 000

E Mail: tox.uk@mmm.com

Website: www.3M.com/uk

1.4. Emergency telephone number

+44 (0)1344 858 000

SECTION 2: Hazard identification

2.1. Classification of the substance or mixture

CLP REGULATION (EC) No 1272/2008

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

3M ESPE Ketac Cem Radiopaque Powder

CLASSIFICATION:

Serious Eye Damage/Eye Irritation, Category 2 - Eye Irrit. 2; H319

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) |

Pictograms



HAZARD STATEMENTS:

H319 Causes serious eye irritation.

PRECAUTIONARY STATEMENTS

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.

2.3. Other hazards

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

SECTION 3: Composition/information on ingredients

Ingredient	CAS Nbr	EC No.	REACH Registration No.	% by Wt	Classification
OXIDE GLASS CHEMICALS (non-fibrous)	65997-17-3	266-046-0		80 - 90	Substance not classified as hazardous
Acrylic acid-maleic acid copolymer	29132-58-9			< 20	Eye Irrit. 2, H319

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

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

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation

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

Skin contact

3M ESPE Ketac Cem Radiopaque Powder

Wash with soap and water. 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.

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 to extinguish.

5.2. Special hazards arising from the substance or mixture

None inherent in this product.

5.3. Advice for fire-fighters

No special protective actions for fire-fighters are anticipated.

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. Observe precautions from other sections.

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.

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

Avoid eye contact. Avoid prolonged or repeated skin contact. 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.

7.2. Conditions for safe storage including any incompatibilities

No special storage requirements.

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

No occupational exposure limit values exist for any of the components listed in Section 3 of this Safety Data Sheet.

Biological limit values

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

Skin/hand protection

See Section 7.1 for additional information on skin protection.

Respiratory protection

Respiratory protection is not required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Solid.
Specific Physical Form:	Powder
Appearance/Odour	Odourless, white powder
Odour threshold	<i>No data available.</i>
pH	<i>Not applicable.</i>
Boiling point/boiling range	<i>Not applicable.</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>Not applicable.</i>
Flammable Limits(UEL)	<i>Not applicable.</i>
Vapour pressure	<i>Not applicable.</i>
Relative density	≥ 1 [Ref Std: WATER=1]
Water solubility	Nil
Solubility- non-water	<i>No data available.</i>

3M ESPE Ketac Cem Radiopaque Powder

Partition coefficient: n-octanol/water	No data available.
Evaporation rate	No data available.
Vapour density	Not applicable.
Decomposition temperature	No data available.
Viscosity	Not applicable.
Density	No data available.

9.2. Other information

EU Volatile Organic Compounds	No data available.
Percent volatile	No data available.

SECTION 10: Stability and reactivity

10.1 Reactivity

This material is considered to be non reactive under normal use conditions

10.2 Chemical stability

Stable.

10.3 Possibility of hazardous reactions

Hazardous polymerisation will not occur.

10.4 Conditions to avoid

None known.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

<u>Substance</u>	<u>Condition</u>
Carbon monoxide.	Not specified.
Carbon dioxide.	Not specified.

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

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

Skin contact

Mechanical skin irritation: Signs/symptoms may include abrasion, redness, pain, and itching.

3M ESPE Ketac Cem Radiopaque Powder

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.

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
OXIDE GLASS CHEMICALS (non-fibrous)	Dermal		LD50 estimated to be > 5,000 mg/kg
OXIDE GLASS CHEMICALS (non-fibrous)	Ingestion		LD50 estimated to be 2,000 - 5,000 mg/kg
Acrylic acid-maleic acid copolymer	Ingestion	Rat	LD50 > 2,000 mg/kg
Acrylic acid-maleic acid copolymer	Dermal	similar health hazards	LD50 Not available

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
OXIDE GLASS CHEMICALS (non-fibrous)	Professional judgement	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
OXIDE GLASS CHEMICALS (non-fibrous)	Professional judgement	No significant irritation

Skin Sensitisation

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

Respiratory Sensitisation

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

Germ Cell Mutagenicity

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

Carcinogenicity

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

Reproductive Toxicity

Reproductive and/or Developmental Effects

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

Target Organ(s)

3M ESPE Ketac Cem Radiopaque Powder**Specific Target Organ Toxicity - single exposure**

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

Specific Target Organ Toxicity - repeated exposure

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

Aspiration Hazard

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

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

SECTION 12: Ecological information

The information below may not agree with the EU material classification in Section 2 and/or the ingredient classifications in Section 3 if specific ingredient classifications are mandated by a competent authority. In addition, statements and data presented in Section 12 are based on UN GHS calculation rules and classifications derived from 3M assessments.

12.1. Toxicity

No product test data available.

Material	CAS Nbr	Organism	Type	Exposure	Test endpoint	Test result
OXIDE GLASS CHEMICALS (non-fibrous)	65997-17-3	Green algae	Experimental	72 hours	EC50	>1,000 mg/l
OXIDE GLASS CHEMICALS (non-fibrous)	65997-17-3	Water flea	Experimental	72 hours	EC50	>1,000 mg/l
OXIDE GLASS CHEMICALS (non-fibrous)	65997-17-3	Zebra Fish	Experimental	96 hours	LC50	>1,000 mg/l
OXIDE GLASS CHEMICALS (non-fibrous)	65997-17-3	Green algae	Experimental	72 hours	NOEC	>=1,000 mg/l
Acrylic acid-maleic acid copolymer	29132-58-9	Zebra Fish	Experimental	96 hours	LC50	>100 mg/l
Acrylic acid-maleic acid copolymer	29132-58-9	Water flea	Experimental	48 hours	EC50	>100 mg/l
Acrylic acid-maleic acid copolymer	29132-58-9	Green algae	Experimental	96 hours	Effect Concentration 10%	32 mg/l
Acrylic acid-maleic acid copolymer	29132-58-9	Water flea	Experimental	21 days	NOEC	350 mg/l
Acrylic acid-maleic acid copolymer	29132-58-9	Zebra Fish	Experimental	14 days	NOEC	40 mg/l

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
OXIDE GLASS CHEMICALS (non-fibrous)	65997-17-3	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Acrylic acid-maleic acid copolymer	29132-58-9	Experimental Biodegradation	28 days	BOD	< 14 % weight	Other methods

12.3 : Bioaccumulative potential

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
OXIDE GLASS	65997-17-3	Data not available	N/A	N/A	N/A	N/A

3M ESPE Ketac Cem Radiopaque Powder

CHEMICALS (non-fibrous)		or insufficient for classification				
Acrylic acid-maleic acid copolymer	29132-58-9	Data not available or insufficient for classification	N/A	N/A	N/A	N/A

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**

See Section 11.1 Information on toxicological effects

Dispose of waste product in a permitted industrial waste facility.

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

EU waste code (product as sold)

180107 Chemicals other than those mentioned in 18 01 06

SECTION 14: Transportation information

70-2011-0340-8

Not hazardous for transportation

70-2011-0340-8

Not hazardous for transportation

ADR/IATA/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

H319 Causes serious eye irritation.

Revision information:

Section 7: Precautions safe handling information information was modified.

Section 12: Component ecotoxicity information information was modified.

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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Document group:	26-9894-2	Version number:	1.00
Revision date:	02/06/2017	Supersedes date:	Initial issue.
Transportation version number: 1.00 (02/06/2017)			

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™ KETAC™ CEM RADIOPAQUE LIQUID

Product Identification Numbers

70-2011-0341-6

7000054679

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

Identified uses

Dental Product

Restrictions on Use

For use only by dental professionals.

1.3. Details of the supplier of the safety data sheet

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

1.4. Emergency telephone number

+44 (0)1344 858 000

SECTION 2: Hazard identification

2.1. Classification of the substance or mixture

CLP REGULATION (EC) No 1272/2008

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

3M™ ESPE™ KETAC™ CEM RADIOPAQUE LIQUID

CLASSIFICATION:

This material is not classified as hazardous according to Regulation (EC) No. 1272/2008, as amended, on classification, labelling, and packaging of substances and mixtures.

2.2. Label elements

CLP REGULATION (EC) No 1272/2008

Not applicable

Notes on labelling

Skin and Eye irritation does not apply based on test data.

2.3. Other hazards

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

SECTION 3: Composition/information on ingredients

Ingredient	CAS Nbr	EC No.	REACH Registration No.	% by Wt	Classification
Non-Hazardous Ingredients	Mixture			80 - 90	Substance not classified as hazardous
Tartaric Acid	87-69-4	201-766-0	01-2119537204-47	10 - 20	Eye Dam. 1, H318

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

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

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation

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

Skin contact

Wash with soap and water. If signs/symptoms develop, get medical attention.

Eye contact

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

If swallowed

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

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

See Section 11.1 Information on toxicological effects

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

Not applicable

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

Material will not burn. Use a fire fighting agent suitable for the surrounding fire.

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.

5.3. Advice for fire-fighters

No special protective actions for fire-fighters are anticipated.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Ventilate the area with fresh air. Observe precautions from other sections.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Contain spill. Working from around the edges of the spill inward, cover with bentonite, vermiculite, or commercially available inorganic absorbent material. Mix in sufficient absorbent until it appears dry. Remember, adding an absorbent material does not remove a physical, health, or environmental hazard. Collect as much of the spilled material as possible. Place in a closed container approved for transportation by appropriate authorities. Clean up residue with water. 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

Avoid prolonged or repeated skin contact. Avoid breathing dust/fume/gas/mist/vapours/spray. Do not eat, drink or smoke when using this product. Wash thoroughly after handling.

7.2. Conditions for safe storage including any incompatibilities

Store away from heat.

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

No occupational exposure limit values exist for any of the components listed in Section 3 of this Safety Data Sheet.

Biological limit values

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

Skin/hand protection

See Section 7.1 for additional information on skin protection.

Respiratory protection

Respiratory protection is not required.

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

Physical state	Liquid.
Specific Physical Form:	Liquid.
Appearance/Odour	Slight characteristic odour, colourless liquid
Odour threshold	<i>No data available.</i>
pH	<i>No data available.</i>
Boiling point/boiling range	approximately 100 °C
Melting point	approximately 0 °C
Flammability (solid, gas)	Not applicable.
Explosive properties	Not classified
Oxidising properties	Not classified
Flash point	No flash point
Autoignition temperature	<i>No data available.</i>
Flammable Limits(LEL)	<i>Not applicable.</i>
Flammable Limits(UEL)	<i>Not applicable.</i>
Vapour pressure	2,133.2 Pa [Ref Std: AIR=1]
Relative density	>=1 [Ref Std: WATER=1]
Water solubility	Complete
Solubility- non-water	<i>No data available.</i>
Partition coefficient: n-octanol/water	<i>No data available.</i>
Evaporation rate	<=1 [Ref Std: BUOAC=1]
Vapour density	<=1 [Ref Std: AIR=1]
Decomposition temperature	<i>No data available.</i>
Viscosity	<i>No data available.</i>

9.2. Other information

Molecular weight	<i>No data available.</i>
Percent volatile	<i>No data available.</i>

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

<u>Substance</u>	<u>Condition</u>
None known.	

Refer to section 5.2 for hazardous decomposition products during combustion.

SECTION 11: Toxicological information

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

11.1 Information on Toxicological effects

Signs and Symptoms of Exposure

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

Inhalation

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

Skin contact

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

Eye contact

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

Ingestion

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

3M™ ESPE™ KETAC™ CEM RADIOPAQUE LIQUID

the data are not sufficient for classification.

Acute Toxicity

Name	Route	Species	Value
Overall product	Ingestion		No data available; calculated ATE >5,000 mg/kg
Tartaric Acid	Dermal	Rat	LD50 > 5,000 mg/kg
Tartaric Acid	Ingestion	Rat	LD50 > 2,000, < 5,000 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Overall product	Rabbit	Minimal irritation

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

Serious Eye Damage/Irritation

Name	Species	Value
Tartaric Acid	In vitro data	Corrosive

Skin Sensitisation

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

Respiratory Sensitisation

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

Germ Cell Mutagenicity

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

Carcinogenicity

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

Reproductive Toxicity

Reproductive and/or Developmental Effects

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

Target Organ(s)

Specific Target Organ Toxicity - single exposure

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

Specific Target Organ Toxicity - repeated exposure

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

Aspiration Hazard

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

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

SECTION 12: Ecological information

The information below may not agree with the EU material classification in Section 2 and/or the ingredient

3M™ ESPE™ KETAC™ CEM RADIOPAQUE LIQUID

classifications in Section 3 if specific ingredient classifications are mandated by a competent authority. In addition, statements and data presented in Section 12 are based on UN GHS calculation rules and classifications derived from 3M assessments.

12.1. Toxicity

No product test data available.

Material	CAS Nbr	Organism	Type	Exposure	Test endpoint	Test result
Tartaric Acid	87-69-4	Zebra Fish	Experimental	96 hours	LC50	>100 mg/l
Tartaric Acid	87-69-4	Water flea	Experimental	48 hours	EC50	93.3 mg/l
Tartaric Acid	87-69-4	Green Algae	Experimental	72 hours	EC50	51.4 mg/l
Tartaric Acid	87-69-4	Green Algae	Experimental	72 hours	NOEC	3.1 mg/l

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Tartaric Acid	87-69-4	Experimental Biodegradation	14 days	BOD	76 % weight	Other methods

12.3 : Bioaccumulative potential

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Tartaric Acid	87-69-4	Estimated Bioconcentration		Log Kow	-1.00	Estimated: Octanol-water partition coefficient

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**

See Section 11.1 Information on toxicological effects

Dispose of waste product in a permitted industrial waste facility. Empty and clean product containers may be disposed as non-hazardous waste. Consult your specific regulations and service providers to determine available options and requirements.

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)

180107 Chemicals other than those mentioned in 18 01 06

SECTION 14: Transportation information

70-2011-0341-6

Not hazardous for transportation

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. The components of this product are in compliance with the new substance notification requirements of CEPA. This product complies with Measures on Environmental Management of New Chemical Substances. All ingredients are listed on or exempt from on China IECSC inventory.

15.2. Chemical Safety Assessment

Not applicable

SECTION 16: Other information

List of relevant H statements

H318 Causes serious eye damage.

Revision information:

No revision information

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