



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 Ketac Cem Easy Mix Powder

Product identification numbers

70-2011-2227-5

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

CLP REGULATION (EC) No 1272/2008

CLASSIFICATION:

This material is exempt from hazard classification according to Regulation (EC) No. 1272/2008, as amended, on classification, labelling, and packaging of substances and mixtures.

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

Indication of danger

Irritant; Xi; R36

For full text of R phrases, see Section 16.

2.2. Label elements

CLP REGULATION (EC) No 1272/2008

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

Symbol(s)



Irritant

Contains:

No ingredients are assigned to the label.

Risk phrases

R36 Irritating to eyes.

Safety phrases None.

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.

2.3. Other hazards

None known.

SECTION 3: Composition/information on ingredients

Ingredient	CAS Nbr	EU Inventory	% by Wt	Classification
Glass, oxide, chemicals	65997-17-3	EINECS 266-046-0	70 - 80	
Acrylic acid-maleic acid copolymer	29132-58-9		20 - 25	Xi:R36 (Self Classified) Eye Irrit. 2, H319 (Self Classified)

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

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

Inhalation

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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

Irritant vapours or gases.

Condition

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. Sweep up. Vacuum or sweep up. Warning: A motor could be an ignition source and cause flammable gases or vapours or dust in the spill area to burn or explode. Seal the container.

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. Do not handle until all safety precautions have been read and understood. 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. Use personal protective equipment (eg. gloves, respirators...) as required. 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.

7.2. Conditions for safe storage including any incompatibilities

No special storage requirements.

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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/m ³ (1 fibers/ml)	
Glass, oxide, chemicals	65997-17-3	Manufacturer determined	TWA(as dust):10 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

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

None required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Solid.
Specific Physical Form:	Fine powder (less than 10 microns).
Appearance/Odour	Different coloured, odourless
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

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Oxidising properties	Not classified
Flash point	<i>Not applicable.</i>
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	≥ 1.0 [<i>Ref Std: WATER=1</i>]
Water solubility	Moderate
Partition coefficient: n-octanol/water	<i>No data available.</i>
Evaporation rate	<i>Not applicable.</i>
Vapour density	<i>Not applicable.</i>
Viscosity	<i>Not applicable.</i>
Density	<i>No data available.</i>
9.2. Other information	
Volatile organic compounds (VOC)	<i>Not applicable.</i>
Percent volatile	<i>Not applicable.</i>
VOC less H2O & exempt solvents	<i>Not applicable.</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

None known.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

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

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

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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

Moderate eye irritation: Signs/symptoms may include redness, swelling, pain, tearing, and blurred or hazy vision.

Skin contact

Mild Skin Irritation: Signs/symptoms may include localized redness, swelling, itching, and dryness.

Inhalation

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

Ingestion

May be harmful if swallowed.

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

Carcinogenicity:

Contains a chemical or chemicals which can cause cancer.

Toxicological Data

Acute Toxicity

Name	Route	Species	Value
Overall product	Ingestion		No test data available; calculated ATE2,370.9 mg/kg
Glass, oxide, chemicals			No data available
Acrylic acid-maleic acid copolymer			No data available

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Glass, oxide, chemicals		No data available
Acrylic acid-maleic acid copolymer		No data available

Serious Eye Damage/Irritation

Name	Species	Value
Glass, oxide, chemicals		No data available
Acrylic acid-maleic acid copolymer		No data available

Skin Sensitisation

Name	Species	Value
Glass, oxide, chemicals		No data available
Acrylic acid-maleic acid copolymer		No data available

Respiratory Sensitisation

Name	Species	Value
Glass, oxide, chemicals		No data available
Acrylic acid-maleic acid copolymer		No data available

Germ Cell Mutagenicity

Name	Route	Value
Glass, oxide, chemicals		No data available
Acrylic acid-maleic acid copolymer		No data available

Carcinogenicity

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Name	Route	Species	Value
Glass, oxide, chemicals	Inhalation		Carcinogenic.
Acrylic acid-maleic acid copolymer			No data available

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

Name	Route	Value	Species	Test result	Exposure Duration
Glass, oxide, chemicals		No data available			
Acrylic acid-maleic acid copolymer		No data available			

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

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Glass, oxide, chemicals	Inhalation	respiratory irritation	Some positive data exist, but the data are not sufficient for classification		Irritation Positive	
Acrylic acid-maleic acid copolymer			No data available			

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Glass, oxide, chemicals			No data available			
Acrylic acid-maleic acid copolymer			No data available			

Aspiration Hazard

Name	Value
Glass, oxide, chemicals	Not an aspiration hazard
Acrylic acid-maleic acid copolymer	Not an aspiration hazard

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.

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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. 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.

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

70-2011-2227-5

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

All applicable chemical ingredients in this material are listed on the European Inventory of Existing Chemical Substances

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(EINECS), or are exempt polymers whose monomers are listed on EINECS. Contact 3M for more information. The components of this product are in compliance with the new substance notification requirements of CEPA.

15.2. Chemical Safety Assessment

Not applicable

SECTION 16: Other information

List of relevant H statements

H319 Causes serious eye irritation.

List of relevant R-phrases

R36 Irritating to eyes.

Revision information:

Revision Changes:

Section 1: Product name was modified.

Risk phrase was modified.

Page Heading: Product name was modified.

Section 9: pH information was modified.

Section 16: UK disclaimer was modified.

Section 1: Product identification numbers heading was modified.

Section 1: Product identification numbers was modified.

Section 9: Evaporation Rate information was modified.

Section 9: Viscosity information was modified.

Section 16: List of relevant R phrase information was modified.

Section 3: Composition/ Information of ingredients table was modified.

Section 9: n-octanol/water coefficient information was modified.

Section 9: Boiling point information was modified.

Section 9: Relative density information was modified.

Section 9: Solubility in water text was modified.

Section 2: Indication of danger information was modified.

Section 12: Contact manufacturer for more detail. was modified.

Section 13: EU waste code (product as sold) information was modified.

Section 1: Address was modified.

Copyright was modified.

Section 9: Flash point information was modified.

Section 9: Melting point information was modified.

Section 9: Flammable limits (LEL) information was modified.

Section 9: Flammable limits (UEL) information was modified.

Section 9: Vapour density value was modified.

Section 9: Vapour pressure value was modified.

Section 9: Density information was modified.

Section 9: Property description for optional properties was modified.

Section 8: Occupational exposure limit table was modified.

Section 8: mg/m³ key was modified.

Aspiration Hazard Table was modified.

Section 11: Acute Toxicity table was modified.

Carcinogenicity Table was modified.

Serious Eye Damage/Irritation Table was modified.

Germ Cell Mutagenicity Table was modified.

Skin Sensitisation Table was modified.

Respiratory Sensitisation Table was modified.

Reproductive Toxicity Table was modified.

Skin Corrosion/Irritation Table was modified.
Target Organs - Repeated Table was modified.
Target Organs - Single Table was modified.
Section 11: Health Effects - Eye information was modified.
Section 11: Health Effects - Skin information was modified.
Section 12: No PBT/vPvB information available warning was modified.
Section 5: Hazardous combustion products table was modified.
Section 6: Accidental release personal information was modified.
Section 6: Accidental release clean-up information was modified.
Section 7: Precautions safe handling information was modified.
Section 10: Hazardous decomposition or by-products table was modified.
Section 13: Standard Phrase Category Waste GHS was modified.
Two-column table displaying the unique list of H Codes and statements (std phrases) for all components of the given material. was modified.
Remark (phrase) was added.
Section 12: Acute aquatic hazard information was added.
Section 12: Chronic aquatic hazard heading was added.
Section 12: Acute aquatic hazard heading was added.
Section 12: Chronic aquatic hazard information was added.
Section 2: Notes on labelling heading was added.
Company logo was added.
Label: CLP Classification - Header was added.
Label: CLP Classification was added.
Telephone header was added.
Company Telephone was added.
Section 2: 2.2 & 2.3. CLP REGULATION heading was added.
Section 9: Autoignition temperature information was added.
Section 2: R phrase reference was added.
Label: Graphic was added.
Label: Graphic was added.
Label: Graphic Text was added.
Section 9: Flammability (solid, gas) information was added.
Company Logo was deleted.
Section 2: Symbol was deleted.
Section 2: Symbols heading was deleted.
Section 11: UN GHS Classification table heading was deleted.

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