

### **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

 $3M^{TM}$  ESPE $^{TM}$  KETAC $^{TM}$  MOLAR EASYMIX LIQUID

#### 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

#### **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

#### 2.2. Label elements

CLP REGULATION (EC) No 1272/2008

Not applicable

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

Not applicable

#### 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.

Dermal and ocular irritation test data indicate this material does not meet the criteria for irritation/corrosion classification.

#### 2.3. Other hazards

None known.

## **SECTION 3: Composition/information on ingredients**

| Ingredient                         | CAS Nbr    | <b>EU Inventory</b> | % by Wt | Classification                       |
|------------------------------------|------------|---------------------|---------|--------------------------------------|
| Non hazardous component            | Mixture    |                     | 50 - 65 |                                      |
| Acrylic acid-maleic acid copolymer | 29132-58-9 |                     | 25 - 40 | Xi:R36 (Self Classified)             |
|                                    |            |                     |         | Eye Irrit. 2, H319 (Self Classified) |
| Tartaric Acid                      | 87-69-4    | EINECS 201-         | 5 - 10  | Xi:R36 (Vendor)                      |
|                                    |            | 766-0               |         |                                      |
|                                    |            |                     |         | Eye Irrit. 2, H319 (Vendor)          |

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

#### 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.

#### **Eve 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

#### 5.2. Special hazards arising from the substance or mixture

None inherent in this product.

#### **Hazardous Decomposition or By-Products**

**Substance** 

Carbon monoxide.

#### Condition

During combustion. 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

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 metal container approved for use in transportation by appropriate authorities. The container must be lined with polyethylene plastic or contain a plastic drum liner made of polyethylene. Clean up residue with water. Cover, but do not seal for 48 hours. 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. Keep away from reactive metals (eg. Aluminum, zinc etc.) to avoid the formation of hydrogen gas that could create an explosion hazard.

### 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.

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#### **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

None required.

### **SECTION 9: Physical and chemical properties**

#### 9.1. Information on basic physical and chemical properties

Physical state Liquid. **Specific Physical Form:** Liquid.

Slight characteristic odour, colourless Appearance/Odour

**Odour threshold** No data available.

pН 0.7 - 1.2100 °C Boiling point/boiling range **Melting point** Not applicable. Not applicable. Flammability (solid, gas) Not classified **Explosive properties Oxidising properties** Not classified Flash point No flash point **Autoignition temperature** No data available. Not applicable. Flammable Limits(LEL) Not applicable.

No data available. Vapour pressure

1.1 - 1.3 [*Ref Std*:WATER=1] Relative density

Complete Water solubility

No data available. Solubility- non-water Partition coefficient: n-octanol/water No data available. **Evaporation rate** No data available. Vapour density No data available. **Decomposition temperature** No data available. Viscosity No data available. **Density** 1.1 - 1.3 g/ml

#### 9.2. Other information

Flammable Limits(UEL)

Data is not available for other physical and chemical parameters.

### **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

**Substance** 

**Condition** 

None known.

Refer to section 5.2 for hazardous decomposition products during combustion.

### **SECTION 11: Toxicological information**

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

#### 11.1 Information on Toxicological effects

Signs and Symptoms of Exposure

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

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.

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 >5,000 mg/kg |
| Acrylic acid-maleic acid copolymer | Dermal    | Professio | LD50 estimated to be > 5,000 mg/kg             |
|                                    |           | nal       |  |
|                                    |           | judgeme   |  |
|                                    |           | nt        |  |
| Acrylic acid-maleic acid copolymer | Ingestion | Rat       | LD50 > 5,000 mg/kg                             |
| Tartaric Acid                      | Ingestion | Mouse     | LD50 4,360 mg/kg                               |

ATE = acute toxicity estimate

#### Skin Corrosion/Irritation

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

#### Serious Eve Damage/Irritation

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

#### 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 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 |
|---|------------|-------------|--|----------|--------------------------------|-------------|
| Acrylic acid-<br>maleic acid<br>copolymer | 29132-58-9 | Water flea  | Experimental   | 48 hours | EC50                           | >100 mg/l   |
| Acrylic acid-<br>maleic acid<br>copolymer | 29132-58-9 | Zebra Fish  | Experimental   | 96 hours | LC50                           | >100 mg/l   |
| Acrylic acid-<br>maleic acid<br>copolymer | 29132-58-9 | Zebra Fish  | Experimental   | 14 days  | NOEC                           | 40 mg/l     |
| Acrylic acid-<br>maleic acid<br>copolymer | 29132-58-9 | Water flea  | Experimental   | 21 days  | NOEC                           | 350 mg/l    |
| Acrylic acid-<br>maleic acid<br>copolymer | 29132-58-9 | Green algae | Experimental   | 96 hours | Effect<br>Concentration<br>10% | 32 mg/l     |
| Tartaric Acid                             | 87-69-4    |             | Data not<br>available or<br>insufficient for<br>classification |          |                                |             |

### 12.2. Persistence and degradability

| Material                                  | CAS Nbr    | Test type  | Duration | Study Type | Test result   | Protocol      |
|---|------------|--|----------|------------|---------------|---------------|
| Non hazardous component                   | Mixture    | Data not<br>available or<br>insufficient for<br>classification | N/A      | N/A        | N/A           | N/A           |
| Acrylic acid-<br>maleic acid<br>copolymer | 29132-58-9 | Experimental Biodegradation                                    | 28 days  | BOD        | < 14 % weight | Other methods |
| 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  |
|---|------------|--|----------|------------|-------------|---|
| Non hazardous component                   | Mixture    | Data not<br>available or<br>insufficient for<br>classification | N/A      | N/A        | N/A         | N/A   |
| Acrylic acid-<br>maleic acid<br>copolymer | 29132-58-9 | Data not<br>available or<br>insufficient for<br>classification | N/A      | N/A        | N/A         | N/A   |
| Tartaric Acid                             | 87-69-4    | Estimated<br>Bioconcentrati<br>on                              |          | Log Kow    | -1.00       | Estimated: Octanol-<br>water partition<br>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.

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/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

All applicable chemical ingredients in this material are listed on the European Inventory of Existing Chemical Substances (EINECS), or are exempt polymers whose monomers are listed on EINECS. Contact 3M for more information. The components of this material are in compliance with the China "Measures on Environmental Management of New Chemical Substance". Certain restrictions may apply. Contact the selling division for additional 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 13: European waste code disclaimer information was added.

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

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

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- Section 14: Transportation classification information was added.
- Section 1: Product identification numbers heading information was deleted.
- Section 1: Product identification numbers information was deleted.
- Section 8: Eye/face protection text information was deleted.
- Sections 3 and 9: Odour, colour, grade information information was modified.
- Section 01: 1.3. Details of the supplier of the safety data sheet heading information was modified.
- Section 2: Contains heading information was deleted.
- Section 2: Safety phrases heading information was deleted.
- Section 1: Product identification numbers heading information was modified.
- Section 2: Risk phrases heading information was deleted.
- Section 15: Symbol information information was deleted.
- Section 8: Respiratory protection information information was added.
- Section 2: Label ingredient information information was deleted.
- Section 12: Component ecotoxicity information information was added.
- Section 12: Persistence and Degradability information information was added.
- Section 12:Bioccumulative potential information information was added.
- Section 12: Component Ecotoxicity table Material column header information was added.
- Section 12: Component Ecotoxicity table CAS No column header information was added.
- Section 12: Component Ecotoxicity table Organism column header information was added.
- Section 12: Component Ecotoxicity table Type column header information was added.
- Section 12: Component Ecotoxicity table Exposure column header information was added.
- Section 12: Component Ecotoxicity table End point column header information was added.
- Section 12: Component Ecotoxicity table Result column header information was added.
- Section 12: Persistence and degradability table Material column header information was added.
- Section 12: Persistence and degradability table CAS No column header information was added.
- Section 12: Persistence and degradability table Test Type column header information was added.
- Section 12: Persistence and degradability table Duration column header information was added.
- Section 12: Persistence and degradability table Test Result column header information was added.
- Section 12: Persistence and degradability table Protocol column header information was added.
- Section 12:Bioccumulative potential table Material column header information was added.
- Section 12:Bioccumulative potential table CAS No column header information was added.
- Section 12:Bioccumulative potential table CAS No column header information was added.
- Section 12:Bioccumulative potential table Test Result column header information was added.
- Section 12:Bioccumulative potential table Protocol column header information was added. Section 12:Bioccumulative potential table Test Type column header information was added.
- Section 2: Special provisions concerning the labelling of certain substances heading information was deleted.
- Section 15: Regulations Inventories information was modified.
- Copyright information was modified.
- Section 9: Flash point information information was modified.
- Prints No Data if Component ecotoxicity information is not present information was deleted.
- Prints No Data if Persistence and Degradability information is not present information was deleted.
- Prints No Data if Bioccumulative potential information is not present information was deleted.
- Section 2: Additional label requirements phrase information was deleted.
- Telephone header information was modified.
- Company Telephone information was modified.
- Section 11: Aspiration Hazard Table information was deleted.
- Section 11: Acute Toxicity table information was modified.
- Section 11: Classification disclaimer information was deleted.
- Section 11: Carcinogenicity Table information was deleted.
- Section 11: Exposure Duration table heading information was deleted.
- Section 11: Serious Eye Damage/Irritation Table information was deleted.
- Section 11: Germ Cell Mutagenicity Table information was deleted.
- Section 11: Skin Sensitization Table information was deleted.
- Section 11: Respiratory Sensitization Table information was deleted.
- Section 11: Reproductive Toxicity Table information was deleted.
- Section 11: Skin Corrosion/Irritation Table information was deleted.

- Section 11: Test Result table heading information was deleted.
- Section 11: Target Organs Repeated Table information was deleted.
- Section 11: Target Organs Single Table information was deleted.
- Section 1: Restrictions on use information information was added.
- Section 1: Restrictions on use header information was added.
- Section 12: Classification Warning information was deleted.
- Section 5: Fire Advice for fire fighters information information was modified.
- Section 6: Accidental release clean-up information information was modified.
- Section 7: Precautions safe handling information information was modified.
- Section 8: Appropriate Engineering controls information information was modified.
- Section 8: Personal Protection Eye information information was modified.
- Section 8: Personal Protection Skin/hand information information was modified.
- Section 8: Personal Protection Respiratory Information information was deleted.
- Section 13: 13.1. Waste disposal note information was modified.
- Section 13: Standard Phrase Category Waste GHS information was modified.
- Section 4: First aid for eye contact information information was modified.
- Section 12: Persistence and degradability table Study Type column header information was added.
- Section 12:Bioccumulative potential table Test Type column header information was added.
- Risk phrase None information was deleted.
- Section 02: EU DPD 'Not applicable' text information was added.
- Section 02: EU CLP 'Not applicable' text information was added.
- Section 10: Hazardous decomposition products during combustion text information was added.
- Section 9: No Data Available Statement information was added.
- Section 11: Disclosed components not in tables text information was added.
- Section 12: Classification Warning information was added.
- Section 11: Classification disclaimer information was added.
- Section 11: Aspiration Hazard text information was added.
- Section 8: 8.1.1 Biological limit values table heading information was added.
- Section 8: BLV information was added.
- Label: Graphic information was deleted.
- Section 02: Graphic information information was deleted.
- Section 11: Respiratory Sensitization text information was added.
- Section 11: Skin Sensitization text information was added.
- Section 11: Serious Eye Damage/Irritation text information was added.
- Section 11: Skin Corrosion/Irritation text information was added.
- Section 11: Germ Cell Mutagenicity text information was added.
- Section 11: Specific Target Organ Toxicity repeated exposure text information was added.
- Section 11: Specific Target Organ Toxicity single exposure text information was added.
- Section 11: Specific Target Organ Toxicity single exposure text information was added.
- Section 11: Carcinogenicity text information was added.

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

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