



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 FIL PLUS APLICAP 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

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:

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

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CLP REGULATION (EC) No 1272/2008

Not applicable

SUPPLEMENTAL INFORMATION

Supplemental Hazard Statements:

EUH210

Safety data sheet available on request.

Notes on labelling

Severe eye irritation classification overridden per test data - material is only considered to be a mild eye irritant

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	EU Inventory	% by Wt	Classification
Non hazardous ingredient	Mixture		40 - 55	
Acrylic acid-maleic acid copolymer	29132-58-9		35 - 55	Eye Irrit. 2, H319 (Self Classified)
Tartaric Acid	87-69-4	201-766-0	5 - 10	Eye Irrit. 2, H319 (Vendor)

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

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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

Irritant vapours or gases.

Condition

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

Collect as much of the spilled material as possible. 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

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

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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.
Appearance/Odour	Slightly acidic odour, colourless
Odour threshold	No data available.
pH	No data available.
Boiling point/boiling range	100 °C
Melting point	Not applicable.
Flammability (solid, gas)	Not applicable.
Explosive properties	Not classified
Oxidising properties	Not classified
Flash point	No flash point
Autoignition temperature	No data available.
Flammable Limits(LEL)	Not applicable.
Flammable Limits(UEL)	Not applicable.
Vapour pressure	No data available.
Relative density	>=1 [Ref Std: WATER=1]
Water solubility	Complete
Solubility- non-water	No data available.
Partition coefficient: n-octanol/water	No data available.
Evaporation rate	No data available.
Vapour density	No data available.
Decomposition temperature	No data available.
Viscosity	<=10,000 mPa-s
Density	No data available.

9.2. Other information

Molecular weight	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

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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:

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 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	Ingestion	Rat	LD50 > 2,000 mg/kg
Acrylic acid-maleic acid copolymer	Dermal	similar health hazards	LD50 Not available

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Tartaric Acid	Dermal		LD50 estimated to be 2,000 - 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 Eye 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-maleic acid	29132-58-9	Water flea	Experimental	48 hours	EC50	>100 mg/l

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copolymer						
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	Zebra Fish	Experimental	14 days	NOEC	40 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	Green algae	Experimental	96 hours	Effect Concentration 10%	32 mg/l
Tartaric Acid	87-69-4		Data not available or insufficient for classification			

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Non hazardous ingredient	Mixture	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Tartaric Acid	87-69-4	Experimental Biodegradation	14 days	BOD	76 % weight	Other methods
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
Non hazardous ingredient	Mixture	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Acrylic acid-maleic acid copolymer	29132-58-9	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
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.

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

ADR/IMDG/IATA: 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. 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.

Revision information:

Section 2.1: Classification information information was deleted.

Label: CLP Classification information was modified.

Section 02: Label Elements: CLP Medical Device information was added.

Label: CLP Supplemental Hazard Statements information was added.

Section 2: Label remarks information was deleted.

Remark (phrase) information was deleted.

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

Section 3: Reference to H statement explanation in Section 016 information was added.

Section 3: Reference to R and H statement explanation in Section 16 information was deleted.

Section 3: Reference to section 15 for Nota info information was deleted.

Section 9: Property description for optional properties information was added.

Section 9: Property description for optional properties information was deleted.

Section 9: Viscosity information information was modified.

Section 11: Acute Toxicity table information was modified.

Section 12: Component ecotoxicity information information was modified.

Section 12: Persistence and Degradability information information was modified.

Section 12: Biocumulative potential information information was modified.

Section 15: Regulations - Inventories information was modified.

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

Section 16: List of relevant R-phrases information was deleted.

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