Safety Information Sheet for Medical Devices

Document group:	26-9894-2	**Version number:**	1.01
Revision date:	01/06/2022	**Supersedes date:**	23/10/2019

A safety data sheet is not required for this Product. This Safety Information Sheet has been created on a voluntary basis.

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

1.1. Product identifier
3M™ Ketac™ Cem radiopaque Liquid (37220, 37221)

Product Identification Numbers
LE-F100-0706-7 70-2011-0045-3 70-2011-0341-6

7000054679 7000129025

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

Identified uses
Medical device; refer to Instructions for Use

Restrictions on Use
For use only by dental professionals.

1.3 Details of the supplier of the safety information sheet for medical devices

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

The health and environmental classifications of this material have been derived using the calculation method, except in cases where test data are available or the physical form impacts classification. Classification(s) based on test data or physical form are noted below, if applicable.
This material has been tested for eye damage/irritation and the test results are reflected in the assigned classification.
This material has been tested for skin corrosion/irritation and the test results do not meet the criteria for classification.

This product is a medical device as defined in Directive 93/42/EEC (MDD) respectively Regulation (EU) 2017/745 (MDR), 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.

2.3. Other hazards

For information on hazards and safe use, please consider the corresponding sections of this document.
This material does not contain any substances that are assessed to be a PBT or vPvB

SECTION 3: Composition/information on ingredients

3.1. Substances
Not applicable

3.2. Mixtures

Ingredient	Identifier(s)	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Water	(CAS-No.) 7732-18-5 (EC-No.) 231-791-2	80 - 90	Substance not classified as hazardous
Tartaric acid (REACH Reg. No.:01-2119537204-47)	(CAS-No.) 87-69-4 (EC-No.) 201-766-0	< 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 SIS

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
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.

SECTION 5: Fire-fighting measures

5.1. Extinguishing media
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

Substance	Condition
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
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
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. Seal the container. Dispose of collected material as soon as possible.

SECTION 7: Handling and storage

Refer to Instructions for Use (IFU) for more information.

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 SIS.

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

Applicable Norms/Standards
Use eye protection conforming to EN 166

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.
Colour	Colourless
Odor	Slight Odor, Characteristic Odour
Melting point/freezing point	approximately 0 ºC
Boiling point/boiling range	approximately 100 ºC
Flammability (solid, gas)	Not applicable.
Flammable Limits(LEL)	*Not applicable.*
Flammable Limits(UEL)	*Not applicable.*
Flash point	Flash point > 93 °C (200 °F)
Autoignition temperature	*No data available.*
Relative density	>=1 [*Ref Std:*WATER=1]
pH	
Kinematic Viscosity	*No data available.*
Water solubility	Complete

9.2. Other information

9.2.2 Other safety characteristics

EU Volatile Organic Compounds	*No data available.*
Evaporation rate	<=1 [*Ref Std:*BUOAC=1]
Molecular weight	*No data available.*
Percent volatile	*No data available.*

SECTION 10: Stability and reactivity

10.1 Reactivity
This material may be reactive with certain agents under certain conditions - see the remaining headings in this section

10.2 Chemical stability
Stable.

10.3 Possibility of hazardous reactions
Hazardous polymerisation will not occur.

10.4 Conditions to avoid
Heat.

10.5 Incompatible materials
None known.

10.6 Hazardous decomposition products

Substance	**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 internal hazard assessments.

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

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

Severe eye irritation: Signs/symptoms may include significant redness, swelling, pain, tearing, cloudy appearance of the cornea, and impaired vision.

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
Tartaric acid	Dermal	Rat	LD50 > 5,000 mg/kg
Tartaric acid	Ingestion	Rat	LD50 4,360 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
Overall product	In vitro data	Severe irritant
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 SIS for additional toxicological information on this material and/or its components.

The product was evaluated by a toxicologist to be safe for its intended use.

11.2. Information on other hazards

This material does not contain any substances that are assessed to be an endocrine disruptor for human health.

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 #	Organism	Type	Exposure	Test endpoint	Test result
Tartaric acid	87-69-4	Activated sludge	Experimental	3 hours		>1,000 mg/l
Tartaric acid	87-69-4	Green algae	Experimental	72 hours	EC50	51.4 mg/l
Tartaric acid	87-69-4	Water flea	Experimental	48 hours	EC50	93.3 mg/l
Tartaric acid	87-69-4	Zebra Fish	Experimental	96 hours	LC50	>100 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	Analogous Compound Biodegradation	14 days	BOD	76 %BOD/ThBOD	OECD 301C - MITI test (I)
Tartaric acid	87-69-4	Experimental Biodegradation	28 days	BOD	85 %BOD/ThBOD	OECD 306(Misc)-Biodegrad. Seaw

12.3 : Bioaccumulative potential

Material	Cas No.	Test type	Duration	Study Type	Test result	Protocol
Tartaric acid	87-69-4	Experimental Bioconcentration		Log Kow	-1.91	OECD 107 log Kow shke flsk mtd

12.4. Mobility in soil

Material	Cas No.	Test type	Study Type	Test result	Protocol
Tartaric acid	87-69-4	Modeled Mobility in Soil	Koc	1 l/kg	ACD/Labs ChemSketch™

12.5. Results of the PBT and vPvB assessment

This material does not contain any substances that are assessed to be a PBT or vPvB

12.6. Endocrine disrupting properties

This material does not contain any substances that are assessed to be an endocrine disruptor for environmental effects

12.7. 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.

Refer to Instructions for Use (IFU) for more information.

EU waste code (product as sold)
180107 Chemicals other than those mentioned in 18 01 06

SECTION 14: Transportation information

Not hazardous for transportation.

	Ground Transport (ADR)	Air Transport (IATA)	Marine Transport (IMDG)
14.1 UN number or ID number	No data available.	No data available.	No data available.
14.2 UN proper shipping name	No data available.	No data available.	No data available.
14.3 Transport hazard class(es)	No data available.	No data available.	No data available.
14.4 Packing group	No data available.	No data available.	No data available.
14.5 Environmental hazards	No data available.	No data available.	No data available.
14.6 Special precautions for user	Please refer to the other sections of the SDS for further information.	Please refer to the other sections of the SDS for further information.	Please refer to the other sections of the SDS for further information.
14.7 Marine Transport in bulk according to IMO instruments	No data available.	No data available.	No data available.
Control Temperature	No data available.	No data available.	No data available.
Emergency Temperature	No data available.	No data available.	No data available.
ADR Classification Code	No data available.	No data available.	No data available.

IMDG Segregation Code	No data available.	No data available.	No data available.

Please contact the address or phone number listed on the first page of the SDS for additional information on the transport/shipment of the material by rail (RID) or inland waterways (ADN).

SECTION 15: Regulatory information

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

Global inventory status
Contact the manufacturer for more information

SECTION 16: Other information

List of relevant H statements

H318	Causes serious eye damage.
H319	Causes serious eye irritation.

Revision information:
A revision has been performed due to the need to update the safety information for the medical device.

The product to which this Safety Information Sheet applies is classified as a medical device according to the EU Medical Device Regulation EU 2017/745. _x000D_
Medical devices which are invasive or used in direct physical contact with the human body are exempt from the requirements of classification and labelling according to Regulation (EC) No. 1272/2008 (CLP; Article 1, paragraph 5)._x000D_
The EU Medical Device Regulation does not foresee the use of Safety Data sheets for medical devices which are invasive or used in direct physical contact with the human body, as the safe use of the product is described through the Instructions for Use and /or the labelling for the product. Nevertheless, the 3M Safety Information Sheet is provided as a further service to customers to provide additional toxicology and chemical information on the product. In case of further questions, please contact your 3M representative listed on the Safety Information Sheet.

3M United Kingdom Safety Information Sheets are available at www.3M.com/uk