



## Safety Information Sheet for Medical Devices

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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 Powder (37210, 37211)

#### Product Identification Numbers

70-2011-0044-6      70-2011-0340-8

7000129024      7000054678

#### 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 by dental professionals only.

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

**Address:** 3M Ireland Limited, The Iveagh Building, The Park, Carrickmines, Dublin 18.  
**Telephone:** +353 1 280 3555  
**E Mail:** tox.uk@mmm.com  
**Website:** www.3M.com

#### 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) 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.

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

<b>Ingredient</b>	<b>CAS Nbr</b>	<b>EC No.</b>	<b>% by Wt</b>	<b>Classification</b>
Glass powder	65997-17-3	266-046-0	80 - 90	Substance not classified as hazardous
Polymeric acid	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 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**

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.

## **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.

#### 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

Appearance	
Physical state	Solid.
Colour	White
Specific Physical Form:	Powder
Odor	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
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>
Relative density	$\geq 1$ [Ref Std:WATER=1]
Water solubility	Nil
Viscosity	<i>Not applicable.</i>
Density	<i>No data available.</i>

### 9.2. Other information

EU Volatile Organic Compounds	<i>No data available.</i>
Percent volatile	<i>No data available.</i>

## 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.

#### 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 ATE2,000 - 5,000 mg/kg
Glass powder	Dermal		LD50 estimated to be > 5,000 mg/kg
Glass powder	Ingestion		LD50 estimated to be 2,000 - 5,000 mg/kg
Polymeric acid	Ingestion	Rat	LD50 > 2,000 mg/kg

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Polymeric acid	Dermal	similar health hazards	LD50 Not available
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ATE = acute toxicity estimate

#### **Skin Corrosion/Irritation**

Name	Species	Value
Glass powder	Professional judgement	No significant irritation

#### **Serious Eye Damage/Irritation**

Name	Species	Value
Glass powder	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)**

#### **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.

## **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**

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No product test data available.

Material	CAS #	Organism	Type	Exposure	Test endpoint	Test result
Glass powder	65997-17-3	Green algae	Experimental	72 hours	EC50	>1,000 mg/l
Glass powder	65997-17-3	Water flea	Experimental	72 hours	EC50	>1,000 mg/l
Glass powder	65997-17-3	Zebra Fish	Experimental	96 hours	LC50	>1,000 mg/l
Glass powder	65997-17-3	Green algae	Experimental	72 hours	NOEC	>=1,000 mg/l
Polymeric acid	29132-58-9	Water flea	Experimental	48 hours	EC50	>100 mg/l
Polymeric acid	29132-58-9	Zebra Fish	Experimental	96 hours	LC50	>100 mg/l
Polymeric acid	29132-58-9	Green algae	Experimental	96 hours	Effect Concentration 10%	32 mg/l
Polymeric acid	29132-58-9	Water flea	Experimental	21 days	NOEC	350 mg/l
Polymeric acid	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
Glass powder	65997-17-3	Data not availbl- insufficient			N/A	
Polymeric acid	29132-58-9	Experimental Biodegradation	28 days	BOD	< 14 % weight	Other methods

## 12.3 : Bioaccumulative potential

Material	Cas No.	Test type	Duration	Study Type	Test result	Protocol
Glass powder	65997-17-3	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Polymeric acid	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

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

## 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.

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

70-2011-0044-6, 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 the manufacturer for more information

## **SECTION 16: Other information**

### **List of relevant H statements**

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 Ireland Safety Information Sheets are available at [www.3M.com](http://www.3M.com)**