

# **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<sup>TM</sup> Ketac<sup>TM</sup> Universal Powder

# 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 profesionals.

#### 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

# CLP REGULATION (EC) No 1272/2008

Not applicable

## 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
Glass, oxide, chemicals	65997-17-3	266-046-0		Substance with a Community
				level exposure limit in the
				workplace

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

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 None known. **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

Evacuate area. 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. Use wet sweeping compound or water to avoid dusting. Sweep up. 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.

#### 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

If a component is disclosed in section 3 but does not appear in the table below, an occupational exposure limit is not available for the component.

Ingredient CAS Nbr Agency Limit type Additional comments

Glass, oxide, chemicals 65997-17-3 UK HSC TWA(as fiber):5 mg/m3(1

fibers/ml)

Glass, oxide, chemicals 65997-17-3 Manufacturer TWA(as dust):10 mg/m3

determined

UK HSC: UK Health and Safety Commission

TWA: Time-Weighted-Average STEL: Short Term Exposure Limit

CEIL: Ceiling

#### **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.

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## 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 Solid.
Specific Physical Form: Powder

Appearance/Odour tooth colored, odorless powders

**Odour threshold** No data available. pН Not applicable. Boiling point/boiling range Not applicable. Melting point No data available. Flammability (solid, gas) Not classified **Explosive properties** Not classified Oxidising properties Not classified Flash point No flash point Autoignition temperature No data available. Not applicable. Flammable Limits(LEL) Flammable Limits(UEL) Not applicable.

**Vapour pressure Relative density**Not applicable.
>=1 [Ref Std:WATER=1]

Water solubility Moderate

Solubility- non-water

Partition coefficient: n-octanol/water

Evaporation rate

Vapour density

Decomposition temperature

No data available.
Not applicable.
No data available.
No data available.
No data available.
Not applicable.

9.2. Other information

Molecular weightNo data available.Percent volatileNot applicable.

# **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:

# 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

Mechanical eye irritation: Signs/symptoms may include pain, redness, tearing and corneal abrasion.

# 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, oxide, chemicals	Dermal		LD50 estimated to be > 5,000 mg/kg
Glass, oxide, chemicals	Ingestion		LD50 estimated to be 2,000 - 5,000 mg/kg

ATE = acute toxicity estimate

#### Skin Corrosion/Irritation

Name	Species	Value
Glass, oxide, chemicals	Professio nal judgemen t	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
Glass, oxide, chemicals	Professio nal judgemen t	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

Name	Route	Value
Glass, oxide, chemicals	In Vitro	Some positive data exist, but the data are not sufficient for classification

Carcinogenicity

Name	Route	Species	Value
Glass, oxide, chemicals	Inhalation	Multiple animal species	Some positive data exist, but the data are 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

<u> </u>						_
Name	Route	Target Organ(s)	Value	Species	Test result	Exposure
						Duration
Glass, oxide, chemicals	Inhalation	respiratory system	Some positive data exist, but the	Human	NOAEL not	occupational
			data are not sufficient for		available	exposure
			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.

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
Glass, oxide,	65997-17-3		Data not			
chemicals			available or			
			insufficient for			
			classification			

# 12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Glass, oxide,	65997-17-3	Data not	N/A	N/A	N/A	N/A
chemicals		available or				
		insufficient for				
		classification				

#### 12.3: Bioaccumulative potential

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Glass, oxide,	65997-17-3	Data not	N/A	N/A	N/A	N/A
chemicals		available or				
		insufficient for				
		classification				

## 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

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# **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

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 material are in compliance with the provisions of the Korea Chemical Control Act. Certain restrictions may apply. Contact the selling division for additional information. The components of this material are in compliance with the provisions of Australia National Industrial Chemical Notification and Assessment Scheme (NICNAS). 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**

## **Revision information:**

No revision information

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