

## **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**  $3M^{TM} ESPE^{TM} CAVIT^{TM}-G$ 

**Product Identification Numbers** 70-2011-0466-1

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 000E Mail:tox.uk@mmm.comWebsite: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:**

Hazardous to the Aquatic Environment (Acute), Category 1 - Aquatic Acute 1; H400

Hazardous to the Aquatic Environment (Chronic), Category 1 - Aquatic Chronic 1; H410

For full text of H phrases, see Section 16.

#### 2.2. Label elements CLP REGULATION (EC) No 1272/2008

**SIGNAL WORD** WARNING.

**Symbols:** GHS09 (Environment) |

**Pictograms** 



HAZARD STATEMENTS:	
H410	Very toxic to aquatic life with long lasting effects.

## PRECAUTIONARY STATEMENTS

<b>Prevention:</b>
P273

Avoid release to the environment.

#### **Disposal:**

P501 Dispose of contents/container in accordance with applicable local/regional/national/international regulations.

8% of the mixture consists of components of unknown acute oral toxicity.

#### Notes on labelling

This material is not considered to be an eye irritant based on the Bovine Corneal Opacity Permeability Assay (BOCP).

#### 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
Zinc oxide	1314-13-2	215-222-5	30 - 50	Aquatic Acute 1, H400,M=10; Aquatic Chronic 1, H410,M=1 (CLP)
2,2'-[Ethane-1,2-diylbis(oxy)]bisethyl diacetate	111-21-7	203-846-0	10 - 20	
Talc	14807-96-6	238-877-9	0 - 20	
Barium Sulfate	7727-43-7	231-784-4	0 - 20	
Zinc Sulphate	7733-02-0	231-793-3	5 - 10	Acute Tox. 4, H302; Eye Dam. 1, H318 (CLP)

				Aquatic Acute 1, H400,M=1; Aquatic Chronic 1, H410,M=1 (Vendor)
Sulfuric acid, calcium salt, hydrate (2:2:1)	10034-76-1	1 -	5	
Poly(vinyl acetate)	9003-20-7	1 -	5	

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

No need for first aid is anticipated.

#### 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

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.

#### Hazardous Decomposition or By-Products

Substance Carbon monoxide. Carbon dioxide. Irritant vapours or gases.

#### Condition

During combustion. 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. For large spill, or spills in confined spaces, provide mechanical ventilation to disperse or exhaust vapours, in accordance with good industrial hygiene practice. Refer to other sections of this SDS for information regarding physical and health hazards, respiratory protection, ventilation, and personal protective equipment.

#### **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.

#### 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. Do not eat, drink or smoke when using this product. Wash thoroughly after handling. Avoid release to the environment.

#### 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
Plaster of Paris	10034-76-1	UK HSC	TWA(as inhalable dust):10	
(Ca(SO4).1/2H2O)			mg/m <sup>3</sup> ;TWA(as respirable	
			dust):4 mg/m <sup>3</sup>	
Talc	14807-96-6	UK HSC	TWA(as respirable dust):1	
			mg/m <sup>3</sup>	
Barium Sulfate	7727-43-7	UK HSC	TWA(as inhalable dust):10	
			mg/m <sup>3</sup> ;TWA(as respirable	
			dust):4 mg/m <sup>3</sup>	

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.

#### 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:	Paste
Appearance/Odour	Slight odour of acetic acid, grey, paste
Odour threshold	No data available.
рН	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	Flash point $> 93 \text{ °C} (200 \text{ °F})$
Autoignition temperature	Not applicable.
Flammable Limits(LEL)	Not applicable.
Flammable Limits(UEL)	Not applicable.
Vapour pressure	Not applicable.
Relative density	2.6 - 2.8 [ <i>Ref Std</i> :WATER=1]
Water solubility	Nil
Solubility- non-water	No data available.
Partition coefficient: n-octanol/water	Not applicable.
Evaporation rate	No data available.
Vapour density	Not applicable.
Decomposition temperature	No data available.
Viscosity	No data available.
Density	2.6 g/cm3 - 3 g/cm3
9.2. Other information	

Percent volatile

Not 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 None known. **Condition** 

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

This product may have a characteristic odour; however, no adverse health effects are anticipated.

#### 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
Zinc oxide	Dermal		LD50 estimated to be > 5,000 mg/kg
Zinc oxide	Inhalation- Dust/Mist (4 hours)	Rat	LC50 > 5.7 mg/l
Zinc oxide	Ingestion	Rat	LD50 > 5,000 mg/kg
Barium Sulfate	Dermal		LD50 estimated to be > 5,000 mg/kg
Barium Sulfate	Ingestion	Rat	LD50 > 15,000 mg/kg
2,2'-[Ethane-1,2-diylbis(oxy)]bisethyl diacetate	Dermal	Rabbit	LD50 9,040 mg/kg

2,2'-[Ethane-1,2-diylbis(oxy)]bisethyl diacetate	Ingestion	Rat	LD50 15,594 mg/kg
Talc	Dermal		LD50 estimated to be > 5,000 mg/kg
Talc	Ingestion		LD50 estimated to be > 5,000 mg/kg
Sulfuric acid, calcium salt, hydrate (2:2:1)	Dermal	Professio nal judgeme nt	LD50 estimated to be > 5,000 mg/kg
Sulfuric acid, calcium salt, hydrate (2:2:1)	Ingestion	similar compoun ds	LD50 estimated to be > 5,000 mg/kg
Poly(vinyl acetate)	Dermal		LD50 estimated to be > 5,000 mg/kg
Poly(vinyl acetate)	Ingestion	Rat	LD50 > 9,700 mg/kg

ATE = acute toxicity estimate

#### Skin Corrosion/Irritation

Name	Species	Value
Zinc oxide	Human	No significant irritation
	and	
	animal	
Talc	Rabbit	No significant irritation
Poly(vinyl acetate)	Rabbit	Mild irritant

#### Serious Eye Damage/Irritation

Name	Species	Value
Zinc oxide	Rabbit	Mild irritant
Barium Sulfate	Rabbit	No significant irritation
Talc	Rabbit	No significant irritation
Poly(vinyl acetate)	similar	Moderate irritant
	health	
	hazards	

#### **Skin Sensitisation**

Name	Species	Value
Zinc oxide	Guinea	Some positive data exist, but the data are not
	pig	sufficient for classification
Poly(vinyl acetate)	Human	Not sensitising

#### **Respiratory Sensitisation**

Name	Species	Value
Talc	Human	Not sensitising

## Germ Cell Mutagenicity

Name	Route	Value
Zinc oxide	In Vitro	Some positive data exist, but the data are not sufficient for classification
Zinc oxide	In vivo	Some positive data exist, but the data are not sufficient for classification
Talc	In Vitro	Not mutagenic
Talc	In vivo	Not mutagenic

#### Carcinogenicity

Name	Route	Species	Value
Talc	Inhalation	Rat	Some positive data exist, but the data are not sufficient for classification
Poly(vinyl acetate)	Not specified.	Multiple animal species	Not carcinogenic

#### **Reproductive Toxicity**

#### **Reproductive and/or Developmental Effects**

Name	Route	Value	Species	Test result	Exposure
					Duration
Zinc oxide	Ingestion	Some positive reproductive/developmental data exist, but the data are not sufficient for classification	Multiple animal species	NOAEL 125 mg/kg/day	premating & during gestation
Talc	Ingestion	Not toxic to development	Rat	NOAEL 1,600 mg/kg	during organogenesis

#### 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 Tar	get Organ	Toxicity -	repeated	exposure	
		_			

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Zinc oxide	Ingestion	nervous system	Some positive data exist, but the data are not sufficient for classification	Rat	NOAEL 600 mg/kg/day	10 days
Zinc oxide	Ingestion	endocrine system   hematopoietic system   kidney and/or bladder	Some positive data exist, but the data are not sufficient for classification	Other	NOAEL 500 mg/kg/day	6 months
Barium Sulfate	Inhalation	pneumoconiosis	Some positive data exist, but the data are not sufficient for classification	Human	NOAEL Not available	occupational exposure
Talc	Inhalation	pneumoconiosis	Causes damage to organs through prolonged or repeated exposure	Human	NOAEL Not available	occupational exposure
Talc	Inhalation	pulmonary fibrosis   respiratory system	Some positive data exist, but the data are not sufficient for classification	Rat	NOAEL 18 mg/m3	113 weeks

#### **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	Туре	Exposure	Test endpoint	Test result
Poly(vinyl	9003-20-7		Data not			
acetate)			available or			
			insufficient for			
			classification			

Zinc Sulphate	7733-02-0	Fish	Experimental	28 days	NOEC	0.09 mg/l
Zinc Sulphate	7733-02-0	Crustacea	Experimental	48 hours	EC50	0.099 mg/l
Zinc Sulphate	7733-02-0	Green Algae	Experimental	72 hours	IC50	0.11 mg/l
Zinc Sulphate	7733-02-0	Algae	Experimental	72 hours	NOEC	0.05 mg/l
Zinc Sulphate	7733-02-0	Water flea	Experimental	48 hours	EC50	0.15 mg/l
Zinc Sulphate	7733-02-0	Crustacea	Experimental	21 days	NOEC	0.11 mg/l
Zinc Sulphate	7733-02-0	Fish	Experimental	96 hours	LC50	0.021 mg/l
2,2'-[Ethane- 1,2- diylbis(oxy)]bi sethyl diacetate	111-21-7	Zebra Fish	Estimated	96 hours	LC50	50 mg/l
2,2'-[Ethane- 1,2- diylbis(oxy)]bi sethyl diacetate	111-21-7	Inland Silverside	Estimated	96 hours	LC50	78 mg/l
Barium Sulfate	7727-43-7	Fish other	Experimental	96 hours	LC50	>100 mg/l
Talc	14807-96-6		Data not available or insufficient for classification			
Sulfuric acid, calcium salt, hydrate (2:2:1)	10034-76-1	Water flea	Laboratory	48 hours	EC50	>1,910 mg/l
Zinc oxide	1314-13-2	Water flea	Experimental	48 hours	EC50	3.2 mg/l
Zinc oxide	1314-13-2	Chinook Salmon	Experimental	96 hours	LC50	0.23 mg/l
Zinc oxide	1314-13-2	Green Algae	Experimental	72 hours	NOEC	0.021 mg/l
Zinc oxide	1314-13-2	Green Algae	Experimental	72 hours	EC50	0.046 mg/l

## 12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
2,2'-[Ethane- 1,2- diylbis(oxy)]bi sethyl diacetate	111-21-7	Estimated Biodegradation	28 days	BOD	77 % weight	OECD 301C - MITI test (I)
2,2'-[Ethane- 1,2- diylbis(oxy)]bi sethyl diacetate	111-21-7	Estimated Biodegradation	28 days	BOD	101 % weight	OECD 301C - MITI test (I)
Zinc Sulphate	7733-02-0	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Talc	14807-96-6	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Sulfuric acid, calcium salt, hydrate (2:2:1)	10034-76-1	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Zinc oxide	1314-13-2	Data not available or	N/A	N/A	N/A	N/A

		insufficient for				
Poly(vinyl acetate)	9003-20-7	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Barium Sulfate	7727-43-7	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
2,2'-[Ethane- 1,2- diylbis(oxy)]bi sethyl diacetate	111-21-7	Estimated Hydrolysis		Hydrolytic half-life	152 days (t 1/2)	Other methods
2,2'-[Ethane- 1,2- diylbis(oxy)]bi sethyl diacetate	111-21-7	Estimated Photolysis		Photolytic half- life (in air)	1 days (t 1/2)	Other methods

#### **12.3 : Bioaccumulative potential**

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Zinc Sulphate	7733-02-0	Experimental BCF - Other	40 days	Bioaccumulatio n factor	13900	Other methods
Talc	14807-96-6	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
2,2'-[Ethane- 1,2- diylbis(oxy)]bi sethyl diacetate	111-21-7	Estimated Bioconcentrati on		Bioaccumulatio n factor	2.6	Other methods
Zinc oxide	1314-13-2	Experimental BCF-Carp	56 days	Bioaccumulatio n factor	<217	OECD 305E - Bioaccumulation flow- through fish test
Sulfuric acid, calcium salt, hydrate (2:2:1)	10034-76-1	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Poly(vinyl acetate)	9003-20-7	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Barium Sulfate	7727-43-7	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

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. As a disposal alternative, incinerate in a permitted waste incineration facility. Empty drums/barrels/containers used for transporting and handling hazardous chemicals (chemical substances/mixtures/preparations classified as Hazardous as per applicable regulations) shall be considered, stored, treated & disposed of as hazardous wastes unless otherwise defined by applicable waste regulations. Consult with the respective regulating authorities to determine the available treatment and disposal facilities.

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**

70-2011-0466-1

ADR/RID: UN3077, NOT RESTRICTED AS PER SPECIAL PROVISION 375, ENVIRONMENTALLY HAZARDOUS SUBSTANCE EXEMPTION, III, --.

**IMDG-CODE:** UN3077, NOT RESTRICTED AS PER IMDG CODE 2.10.2.7, MARINE POLLUTANT EXCEPTION, III, IMDG-Code segregation code: NONE, EMS: --.

ICAO/IATA: UN3077, NOT RESTRICTED AS PER SPECIAL PROVISION A197, ENVIRONMENTALLY HAZARDOUS SUBSTANCE EXCEPTION, III.

## **SECTION 15: Regulatory information**

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

Carcinogenicity

Ingredient Poly(vinyl acetate) <u>CAS Nbr</u> 9003-20-7 <u>Classification</u> Gr. 3: Not classifiable **<u>Regulation</u>** International Agency for Research on Cancer

#### **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.

**15.2. Chemical Safety Assessment** Not applicable

## **SECTION 16: Other information**

List of relevant H statements

H302	Harmful if swallowed.
H318	Causes serious eye damage.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

#### **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