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™ Cavit™ (44351, 44030)

Product Identification Numbers

70-2011-0462-0	70-2011-2004-8	70-2011-3642-4	70-2011-4083-0
7000030667	7000055089	7000054919	7000055217

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 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:
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

Prevention:

P273	Avoid release to the environment.

Disposal:

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

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	EC No.	% by Wt	Classification
Zinc oxide	1314-13-2	215-222-5	40 - 60	Aquatic Acute 1, H400,M=1; Aquatic Chronic 1, H410,M=1
Calcium salt	10034-76-1		15 - 35	Substance with an occupational exposure limit
Zinc salt	7733-02-0	231-793-3	1 - 20	Acute Tox. 4, H302; Eye Dam. 1, H318; Aquatic Acute 1, H400,M=1; Aquatic

				Chronic 1, H410,M=1
Diacetate	111-21-7	203-846-0	10 - 20	Substance not classified as hazardous
Resin	9003-20-7		1 - 10	Substance not classified as hazardous

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
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.

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	Condition
Carbon monoxide	During combustion.
Carbon dioxide.	During combustion.
Irritant vapours or gases.	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 SIS 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.

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
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 (Ca(SO4).1/2H2O)	10034-76-1	UK HSC	TWA(as inhalable dust):10 mg/m³;TWA(as respirable dust):4 mg/m³	

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 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
None required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	
Physical state	Solid.
Colour	Pink
Specific Physical Form:	Paste

Odor	Slight Acetic Acid
pH	*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	*Not applicable.*
Flammable Limits(LEL)	*Not applicable.*
Flammable Limits(UEL)	*Not applicable.*
Relative density	2.6 - 3 [*Ref Std:*WATER=1]
Water solubility	Nil
Viscosity	*No data available.*
Density	2.6 g/cm3 - 3 g/cm3

9.2. Other information

EU Volatile Organic Compounds	*No data available.*
Molecular weight	*No data available.*
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	**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
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
Calcium salt	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Calcium salt	Ingestion	similar compounds	LD50 estimated to be > 5,000 mg/kg
Diacetate	Dermal	Rabbit	LD50 9,040 mg/kg
Diacetate	Ingestion	Rat	LD50 15,594 mg/kg
Resin	Dermal		LD50 estimated to be > 5,000 mg/kg
Resin	Ingestion	Rat	LD50 > 9,700 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Zinc oxide	Human and animal	No significant irritation
Resin	Rabbit	Mild irritant

Serious Eye Damage/Irritation

Name	Species	Value
Zinc oxide	Rabbit	Mild irritant
Resin	similar health hazards	Moderate irritant

Skin Sensitisation

Name	Species	Value
Zinc oxide	Guinea pig	Not classified
Resin	Human	Not classified

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
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

Carcinogenicity

Name	Route	Species	Value
Resin	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	Not classified for reproduction and/or development	Multiple animal species	NOAEL 125 mg/kg/day	premating & during gestation

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

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Zinc oxide	Ingestion	nervous system	Not classified	Rat	NOAEL 600 mg/kg/day	10 days
Zinc oxide	Ingestion	endocrine system | hematopoietic system | kidney and/or bladder	Not classified	Other	NOAEL 500 mg/kg/day	6 months

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

No product test data available.

Material	CAS #	Organism	Type	Exposure	Test endpoint	Test result
Zinc oxide	1314-13-2	Green Algae	Estimated	72 hours	EC50	0.052 mg/l
Zinc oxide	1314-13-2	Rainbow trout	Estimated	96 hours	LC50	0.21 mg/l
Zinc oxide	1314-13-2	Water flea	Estimated	48 hours	EC50	0.07 mg/l
Zinc oxide	1314-13-2	Green Algae	Estimated	72 hours	NOEC	0.006 mg/l

Zinc oxide	1314-13-2	Water flea	Estimated	7 days	NOEC	0.02 mg/l
Calcium salt	10034-76-1	Algae or other aquatic plants	Estimated	96 hours	EC50	3,400 mg/l
Calcium salt	10034-76-1	Bluegill	Estimated	96 hours	LC50	>3,180 mg/l
Calcium salt	10034-76-1	Water flea	Estimated	48 hours	EC50	>2,100 mg/l
Calcium salt	10034-76-1	Water flea	Estimated	21 days	NOEC	1,350 mg/l
Diacetate	111-21-7	Fathead minnow	Experimental	96 hours	LC50	185 mg/l
Diacetate	111-21-7	Green algae	Experimental	72 hours	EC50	>100 mg/l
Diacetate	111-21-7	Water flea	Experimental	48 hours	EC50	>100 mg/l
Diacetate	111-21-7	Green algae	Experimental	72 hours	NOEC	100 mg/l
Zinc salt	7733-02-0	Rainbow trout	Estimated	96 hours	LC50	0.42 mg/l
Zinc salt	7733-02-0		Experimental	48 hours	EC50	0.099 mg/l
Zinc salt	7733-02-0	Green Algae	Experimental	72 hours	EC50	0.104 mg/l
Zinc salt	7733-02-0	Water flea	Experimental	48 hours	EC50	0.15 mg/l
Zinc salt	7733-02-0	Diatom	Experimental	72 hours	NOEC	0.05 mg/l
Zinc salt	7733-02-0	Green Algae	Experimental	72 hours	NOEC	0.012 mg/l
Zinc salt	7733-02-0	Water flea	Experimental	7 days	NOEC	0.032 mg/l
Resin	9003-20-7		Data not available or insufficient for classification			

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Zinc oxide	1314-13-2	Data not availbl-insufficient			N/A	
Calcium salt	10034-76-1	Data not availbl-insufficient			N/A	
Diacetate	111-21-7	Experimental Biodegradation	28 days	BOD	60 % BOD/ThBOD	OECD 301C - MITI test (I)
Zinc salt	7733-02-0	Data not availbl-insufficient			N/A	
Resin	9003-20-7	Data not availbl-insufficient			N/A	

12.3 : Bioaccumulative potential

Material	Cas No.	Test type	Duration	Study Type	Test result	Protocol
Zinc oxide	1314-13-2	Experimental BCF-Carp	56 days	Bioaccumulation factor	≤217	OECD 305E - Bioaccumulation flow-through fish test
Calcium salt	10034-76-1	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Diacetate	111-21-7	Experimental Bioconcentration		Log Kow	0.03	Other methods
Zinc salt	7733-02-0	Experimental BCF-Carp	56 days	Bioaccumulation factor	242	Other methods
Resin	9003-20-7	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

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)
180106* Chemicals consisting of or containing dangerous substances.

SECTION 14: Transportation information

70-2011-0462-0

70-2011-2004-8

70-2011-3642-4

70-2011-4083-0

Exemption: For vessels containing a net quantity of 5 l or a net mass of 5 kg or less per single or inner packaging , special provision 375 (ADR), exemption per 2.10.2.7 (IMDG) or special provision A197 (IATA) may be applied, if applicable
ADR: UN3077; Environmentally Hazardous Substance, Solid, N.O.S; 9; III; (E); M7.
IATA: UN3077; Environmentally Hazardous Substance, Solid, N.O.S; 9; III; FA, SF.
IMDG: UN3077; Environmentally Hazardous Substance, Solid, N.O.S; 9; III; FA, SF.

SECTION 15: Regulatory information

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

Carcinogenicity
Contact the manufacturer for more information

Global inventory status
Contact the manufacturer for more information

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:

Revision information not available

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