Safety Information Sheet for Medical Devices

Document group:	31-4087-8	**Version number:**	1.00
Revision date:	23/06/2022	**Supersedes date:**	Initial issue.

Transportation version number:

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

IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier
3M™ Ketac™ Cem Plus Automix Cement (3536/3536TK/3536SK)

Product Identification Numbers

70-2010-8891-4	70-2010-8892-2	70-2010-8922-7
7000054643	7000054637	7000054636

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 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

This product is a kit or a multipart product which consists of multiple, independently packaged components. Safety Information Sheet for Medical Devices for each of these components is included. Please do not separate the component Safety Information Sheet for Medical Devices from this cover page. The document numbers of the Safety Information Sheet for Medical Devices for components of this product are:

31-4085-2, 31-4086-0

TRANSPORTATION INFORMATION

KIT LABEL

2.1. Classification of the substance or mixture
Please refer to Kit Components

Revision information:
Revision information not available

Safety Information Sheet for Medical Devices

Document group:	31-4085-2	**Version number:**	1.00
Revision date:	20/06/2022	**Supersedes date:**	Initial issue.

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 PLUS CEMENT PASTE A

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 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:
Skin Sensitization, Category 1 - Skin Sens. 1; H317

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

Ingredients:

Ingredient	CAS Nbr	EC No.	% by Wt
Methacrylate (HEMA)	868-77-9	212-782-2	< 10
Allylthiourea	109-57-9	203-683-5	< 1
Phenethyl alcohol	50438-75-0		< 1

HAZARD STATEMENTS:
H317 May cause an allergic skin reaction.

PRECAUTIONARY STATEMENTS

Prevention:
P280E Wear protective gloves.

Response:
P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

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]
Silane treated glass powder	None	70 - 80	Substance not classified as hazardous
Water	(CAS-No.) 7732-18-5	10 -	Substance not classified as hazardous

	(EC-No.) 231-791-2	20	
Methacrylate (HEMA)	(CAS-No.) 868-77-9 (EC-No.) 212-782-2	< 10	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317 Nota D
Titanium dioxide	(CAS-No.) 13463-67-7 (EC-No.) 236-675-5	< 0.5	Carc. 2, H351 (inhalation)
Silane treated silica	(CAS-No.) 68909-20-6 (EC-No.) 272-697-1	< 2	Substance with a national occupational exposure limit
Allylthiourea	(CAS-No.) 109-57-9 (EC-No.) 203-683-5	< 1	Acute Tox. 3, H301 Skin Sens. 1, H317 Aquatic Chronic 3, H412
Phenethyl alcohol	(CAS-No.) 50438-75-0	< 1	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317 STOT SE 3, H335

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
Immediately wash with soap and water. Remove contaminated clothing and wash before reuse. If signs/symptoms develop, get medical attention.

Eye contact
No need for first aid is anticipated.

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.

5.3. Advice for fire-fighters
Wear full protective clothing, including helmet, self-contained, positive pressure or pressure demand breathing apparatus, bunker coat and pants, bands around arms, waist and legs, face mask, and protective covering for exposed areas of the head.

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. 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
Titanium dioxide	13463-67-7	UK HSC	TWA(respirable):4 mg/m3;TWA(Inhalable):10 mg/m3	
Silicon dioxide	68909-20-6	UK HSC	TWA(as respirable dust):2.4 mg/m3;TWA(as inhalable dust):6 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.

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	Solid.
Specific Physical Form:	Paste
Colour	Off-White, Yellow
Odor	Characteristic Odour
Melting point/freezing point	*No data available.*
Boiling point/boiling range	*No data available.*
Flammability (solid, gas)	Not classified
Flammable Limits(LEL)	*No data available.*
Flammable Limits(UEL)	*No data available.*
Flash point	No flash point
Autoignition temperature	*No data available.*
Relative density	1.5 [*Ref Std:*WATER=1]
pH	*substance/mixture is non-soluble (in water)*
Kinematic Viscosity	*No data available.*
Water solubility	Negligible
Density	1.5 g/cm3

9.2. Other information

9.2.2 Other safety characteristics

EU Volatile Organic Compounds	*No data available.*
Evaporation rate	*No data available.*
Molecular weight	*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
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
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. Allergic skin reaction (non-photo induced): Signs/symptoms may include redness, swelling, blistering, and itching.

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.

Additional Health Effects:

Carcinogenicity:
Exposures needed to cause the following health effect(s) are not expected during normal, intended use:
Contains a chemical or chemicals which can cause cancer.

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
Methacrylate (HEMA)	Dermal	Rabbit	LD50 > 5,000 mg/kg
Methacrylate (HEMA)	Ingestion	Rat	LD50 5,564 mg/kg
Silane treated silica	Dermal	Rabbit	LD50 > 5,000 mg/kg
Silane treated silica	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 0.691 mg/l
Silane treated silica	Ingestion	Rat	LD50 > 5,110 mg/kg
Titanium dioxide	Dermal	Rabbit	LD50 > 10,000 mg/kg
Titanium dioxide	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 6.82 mg/l
Titanium dioxide	Ingestion	Rat	LD50 > 10,000 mg/kg
Allylthiourea	Ingestion	Rat	LD50 200 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Methacrylate (HEMA)	Rabbit	Minimal irritation
Silane treated silica	Rabbit	No significant irritation
Titanium dioxide	Rabbit	No significant irritation
Allylthiourea	Professional judgement	Minimal irritation

Serious Eye Damage/Irritation

Name	Species	Value
Methacrylate (HEMA)	Rabbit	Moderate irritant
Silane treated silica	Rabbit	No significant irritation
Titanium dioxide	Rabbit	No significant irritation
Allylthiourea	Professional judgement	Mild irritant

Skin Sensitisation

Name	Species	Value
Methacrylate (HEMA)	Human and animal	Sensitising
Silane treated silica	Human and animal	Not classified
Titanium dioxide	Human and animal	Not classified
Allylthiourea	Professional judgement	Sensitising

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
Methacrylate (HEMA)	In vivo	Not mutagenic
Methacrylate (HEMA)	In Vitro	Some positive data exist, but the data are not sufficient for classification
Silane treated silica	In Vitro	Not mutagenic
Titanium dioxide	In Vitro	Not mutagenic
Titanium dioxide	In vivo	Not mutagenic
Allylthiourea	In Vitro	Not mutagenic

Carcinogenicity

Name	Route	Species	Value
Silane treated silica	Not specified.	Mouse	Some positive data exist, but the data are not sufficient for classification
Titanium dioxide	Ingestion	Multiple animal species	Not carcinogenic
Titanium dioxide	Inhalation	Rat	Carcinogenic.
Allylthiourea	Ingestion	Rat	Some positive data exist, but the data are not sufficient for classification

Reproductive Toxicity

Reproductive and/or Developmental Effects

Name	Route	Value	Species	Test result	Exposure Duration
Methacrylate (HEMA)	Ingestion	Not classified for female reproduction	Rat	NOAEL 1,000 mg/kg/day	premating & during gestation
Methacrylate (HEMA)	Ingestion	Not classified for male reproduction	Rat	NOAEL 1,000 mg/kg/day	49 days
Methacrylate (HEMA)	Ingestion	Not classified for development	Rat	NOAEL 1,000 mg/kg/day	premating & during gestation
Silane treated silica	Ingestion	Not classified for female reproduction	Rat	NOAEL 509 mg/kg/day	1 generation
Silane treated silica	Ingestion	Not classified for male reproduction	Rat	NOAEL 497 mg/kg/day	1 generation
Silane treated silica	Ingestion	Not classified for development	Rat	NOAEL 1,350	during

				mg/kg/day	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 Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Silane treated silica	Inhalation	respiratory system | silicosis	Not classified	Human	NOAEL Not available	occupational exposure
Titanium dioxide	Inhalation	respiratory system	Some positive data exist, but the data are not sufficient for classification	Rat	LOAEL 0.01 mg/l	2 years
Titanium dioxide	Inhalation	pulmonary fibrosis	Not classified	Human	NOAEL Not available	occupational exposure
Allylthiourea	Ingestion	endocrine system	Not classified	Rat	NOAEL 23 mg/kg/day	15 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.

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
Methacrylate (HEMA)	868-77-9	Turbot	Analogous Compound	96 hours	LC50	833 mg/l
Methacrylate (HEMA)	868-77-9	Fathead minnow	Experimental	96 hours	LC50	227 mg/l
Methacrylate (HEMA)	868-77-9	Green algae	Experimental	72 hours	EC50	710 mg/l
Methacrylate (HEMA)	868-77-9	Water flea	Experimental	48 hours	EC50	380 mg/l
Methacrylate (HEMA)	868-77-9	Green algae	Experimental	72 hours	NOEC	160 mg/l
Methacrylate (HEMA)	868-77-9	Water flea	Experimental	21 days	NOEC	24.1 mg/l
Methacrylate (HEMA)	868-77-9		Experimental	16 hours	EC0	>3,000 mg/l
Methacrylate (HEMA)	868-77-9		Experimental	18 hours	LD50	<98 mg per kg of bodyweight

Titanium dioxide	13463-67-7	Activated sludge	Experimental	3 hours	NOEC	>=1,000 mg/l
Titanium dioxide	13463-67-7	Diatom	Experimental	72 hours	EC50	>10,000 mg/l
Titanium dioxide	13463-67-7	Fathead minnow	Experimental	96 hours	LC50	>100 mg/l
Titanium dioxide	13463-67-7	Water flea	Experimental	48 hours	EC50	>100 mg/l
Titanium dioxide	13463-67-7	Diatom	Experimental	72 hours	NOEC	5,600 mg/l
Silane treated silica	68909-20-6	Algae or other aquatic plants	Estimated	72 hours	EC50	>100 mg/l
Allylthiourea	109-57-9	Water flea	Experimental	24 hours	LC50	39 mg/l
Phenethyl alcohol	50438-75-0		Data not available or insufficient for classification			N/A

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Methacrylate (HEMA)	868-77-9	Experimental Hydrolysis		Hydrolytic half-life basic pH	10.9 days (t 1/2)	OECD 111 Hydrolysis func of pH
Methacrylate (HEMA)	868-77-9	Experimental Biodegradation	28 days	BOD	84 %BOD/COD	OECD 301D - Closed bottle test
Titanium dioxide	13463-67-7	Data not availbl-insufficient	N/A	N/A	N/A	N/A
Silane treated silica	68909-20-6	Data not availbl-insufficient	N/A	N/A	N/A	N/A
Allylthiourea	109-57-9	Estimated Biodegradation	28 days	BOD	35 %BOD/ThBOD	OECD 301F - Manometric respirometry
Phenethyl alcohol	50438-75-0	Estimated Biodegradation	28 days	BOD	7 % weight	OECD 301C - MITI test (I)

12.3 : Bioaccumulative potential

Material	Cas No.	Test type	Duration	Study Type	Test result	Protocol
Methacrylate (HEMA)	868-77-9	Experimental Bioconcentration		Log Kow	0.42	OECD 107 log Kow shke flsk mtd
Titanium dioxide	13463-67-7	Experimental BCF - Carp	42 days	Bioaccumulation factor	9.6	Non-standard method
Silane treated silica	68909-20-6	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Allylthiourea	109-57-9	Estimated Bioconcentration		Bioaccumulation factor	3.89	Estimated: Bioconcentration factor
Phenethyl alcohol	50438-75-0	Estimated Bioconcentration		Bioaccumulation factor	3.6	Estimated: Bioconcentration factor

12.4. Mobility in soil

Material	Cas No.	Test type	Study Type	Test result	Protocol
Methacrylate (HEMA)	868-77-9	Experimental Mobility in Soil	Koc	42.7 l/kg	
Allylthiourea	109-57-9	Estimated Mobility in Soil	Koc	33 l/kg	Episuite™
Phenethyl alcohol	50438-75-0	Estimated Mobility in Soil	Koc	88 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)
180106* Chemicals consisting of or containing dangerous substances.

SECTION 14: Transportation information

	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

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

H301	Toxic if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H351i	Suspected of causing cancer by inhalation.
H412	Harmful 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 United Kingdom Safety Information Sheets are available at www.3M.com/uk

Safety Information Sheet for Medical Devices

Document group:	31-4086-0	**Version number:**	2.00
Revision date:	23/06/2022	**Supersedes date:**	23/06/2022

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 PLUS CEMENT PASTE B

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 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:
Skin Corrosion/Irritation, Category 2 - Skin Irrit. 2; H315

Serious Eye Damage/Eye Irritation, Category 2 - Eye Irrit. 2; H319
Respiratory Sensitization, Category 1 - Resp. Sens. 1; H334
Skin Sensitization, Category 1 - Skin Sens. 1; H317

For full text of H phrases, see Section 16.

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

SIGNAL WORD
DANGER.

Symbols
GHS08 (Health Hazard) |

Pictograms

Ingredients:

Ingredient	CAS Nbr	EC No.	% by Wt
Methacrylate (HEMA)	868-77-9	212-782-2	10 - 30
Persulfate	7727-21-1	231-781-8	1 - 5
Dimethacrylate (EGDMA)	97-90-5	202-617-2	< 0.5

HAZARD STATEMENTS:

H315	Causes skin irritation.
H319	Causes serious eye irritation.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H317	May cause an allergic skin reaction.

PRECAUTIONARY STATEMENTS

Prevention:

P261G	Avoid breathing vapours or dust.
P280E	Wear protective gloves.

Response:

P304 + P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.
P342 + P311	If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician.

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]
Silane treated ceramic	(CAS-No.) 444758-98-9	30 - 40	Substance not classified as hazardous
Polymeric acid	(CAS-No.) 25948-33-8	10 - 30	Substance not classified as hazardous
Methacrylate (HEMA)	(CAS-No.) 868-77-9 (EC-No.) 212-782-2	10 - 30	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317 Nota D
Water	(CAS-No.) 7732-18-5 (EC-No.) 231-791-2	5 - 15	Substance not classified as hazardous
Persulfate	(CAS-No.) 7727-21-1 (EC-No.) 231-781-8	1 - 5	Ox. Sol. 3, H272 Acute Tox. 4, H302 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Resp. Sens. 1, H334 Skin Sens. 1, H317 STOT SE 3, H335
Potassium salt	(CAS-No.) 7778-77-0 (EC-No.) 231-913-4	1 - 5	Substance not classified as hazardous
Dimethacrylate	(EC-No.) 931-227-1	1 - 5	Eye Irrit. 2, H319
BHT	(CAS-No.) 128-37-0 (EC-No.) 204-881-4	< 0.5	Aquatic Chronic 1, H410,M=1 Aquatic Acute 1, H400,M=1
Dimethacrylate (EGDMA)	(CAS-No.) 97-90-5 (EC-No.) 202-617-2	< 0.5	Skin Sens. 1B, H317 STOT SE 3, H335 Nota D Aquatic Chronic 3, H412

Any entry in the Identifier(s) column that begins with the numbers 6, 7, 8, or 9 are a Provisional List Number provided by ECHA pending publication of the official EC Inventory Number for the substance.
Please see section 16 for the full text of any H statements referred to in this section

Specific Concentration Limits

Ingredient	Identifier(s)	Specific Concentration Limits
Dimethacrylate (EGDMA)	(CAS-No.) 97-90-5 (EC-No.) 202-617-2	(C >= 10%) STOT SE 3, H335

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

Immediately wash with soap and water. Remove contaminated clothing and wash before reuse. 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.

Hazardous Decomposition or By-Products

Substance	Condition
Carbon monoxide	During combustion.
Carbon dioxide.	During combustion.

5.3. Advice for fire-fighters
Wear full protective clothing, including helmet, self-contained, positive pressure or pressure demand breathing apparatus, bunker coat and pants, bands around arms, waist and legs, face mask, and protective covering for exposed areas of the head.

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. 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
BHT	128-37-0	UK HSC	TWA:10 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.

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	Solid.
Specific Physical Form:	Paste
Colour	Transparent Yellow
Odor	Characteristic Odour
Melting point/freezing point	*Not applicable.*
Boiling point/boiling range	*Not applicable.*
Flammability (solid, gas)	Not classified
Flammable Limits(LEL)	*No data available.*
Flammable Limits(UEL)	*No data available.*
Flash point	No flash point
Autoignition temperature	*No data available.*
Relative density	1.5 [*Ref Std:*WATER=1]
pH	*substance/mixture is non-soluble (in water)*
Kinematic Viscosity	*No data available.*
Water solubility	Negligible
Density	1.5 g/cm3

9.2. Other information

9.2.2 Other safety characteristics

EU Volatile Organic Compounds	*No data available.*
Evaporation rate	*No data available.*

Molecular weight *Not applicable.*

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. Allergic respiratory reaction: Signs/symptoms may include difficulty breathing, wheezing, cough, and tightness of chest.

Skin contact
Mild Skin Irritation: Signs/symptoms may include localised redness, swelling, itching, and dryness. Allergic skin reaction (non-photo induced): Signs/symptoms may include redness, swelling, blistering, 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
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	Inhalation-Dust/Mist(4 hr)		No data available; calculated ATE >12.5 mg/l
Overall product	Ingestion		No data available; calculated ATE >5,000 mg/kg
Silane treated ceramic	Dermal		LD50 estimated to be > 5,000 mg/kg
Silane treated ceramic	Ingestion		LD50 estimated to be 2,000 - 5,000 mg/kg
Polymeric acid	Ingestion	Rat	LD50 > 5,000 mg/kg
Polymeric acid	Dermal	similar health hazards	LD50 estimated to be > 5,000 mg/kg
Methacrylate (HEMA)	Dermal	Rabbit	LD50 > 5,000 mg/kg
Methacrylate (HEMA)	Ingestion	Rat	LD50 5,564 mg/kg
Dimethacrylate	Ingestion	Rat	LD50 > 2,000 mg/kg
Potassium salt	Dermal	Rabbit	LD50 > 4,640 mg/kg
Potassium salt	Ingestion	Rat	LD50 > 4,640 mg/kg
Persulfate	Dermal	Rabbit	LD50 > 10,000 mg/kg
Persulfate	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 10.7 mg/l
Persulfate	Ingestion	Rat	LD50 1,130 mg/kg
Dimethacrylate (EGDMA)	Dermal	Professional judgement	LD50 estimated to be 2,000 - 5,000 mg/kg
Dimethacrylate (EGDMA)	Ingestion	Rat	LD50 3,300 mg/kg
BHT	Dermal	Rat	LD50 > 2,000 mg/kg
BHT	Ingestion	Rat	LD50 > 2,930 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Silane treated ceramic	similar compounds	No significant irritation
Methacrylate (HEMA)	Rabbit	Minimal irritation
Dimethacrylate	Rabbit	No significant irritation
Dimethacrylate (EGDMA)	Professional judgement	Mild irritant
BHT	Human and animal	Minimal irritation

Serious Eye Damage/Irritation

Name	Species	Value
Silane treated ceramic	similar compounds	Mild irritant
Methacrylate (HEMA)	Rabbit	Moderate irritant
Dimethacrylate	In vitro data	Severe irritant
Dimethacrylate (EGDMA)	Not available	Moderate irritant
BHT	Rabbit	Mild irritant

Skin Sensitisation

Name	Species	Value
Silane treated ceramic	similar compounds	Not classified
Methacrylate (HEMA)	Human and animal	Sensitising
Dimethacrylate	Mouse	Not classified
Dimethacrylate (EGDMA)	Guinea pig	Sensitising
BHT	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
Methacrylate (HEMA)	In vivo	Not mutagenic
Methacrylate (HEMA)	In Vitro	Some positive data exist, but the data are not sufficient for classification
Dimethacrylate (EGDMA)	In Vitro	Some positive data exist, but the data are not sufficient for classification
BHT	In Vitro	Not mutagenic
BHT	In vivo	Not mutagenic

Carcinogenicity

Name	Route	Species	Value
Silane treated ceramic	Inhalation	similar compounds	Some positive data exist, but the data are not sufficient for classification
BHT	Ingestion	Multiple animal species	Some positive data exist, but the data are not sufficient for classification

Reproductive Toxicity

Reproductive and/or Developmental Effects

Name	Route	Value	Species	Test result	Exposure Duration
Methacrylate (HEMA)	Ingestion	Not classified for female reproduction	Rat	NOAEL 1,000 mg/kg/day	premating & during gestation
Methacrylate (HEMA)	Ingestion	Not classified for male reproduction	Rat	NOAEL 1,000 mg/kg/day	49 days
Methacrylate (HEMA)	Ingestion	Not classified for development	Rat	NOAEL 1,000 mg/kg/day	premating & during gestation
BHT	Ingestion	Not classified for female reproduction	Rat	NOAEL 500 mg/kg/day	2 generation
BHT	Ingestion	Not classified for male reproduction	Rat	NOAEL 500 mg/kg/day	2 generation
BHT	Ingestion	Not classified for development	Rat	NOAEL 100 mg/kg/day	2 generation

Target Organ(s)

Specific Target Organ Toxicity - single exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Polymeric acid	Ingestion	nervous system	Not classified	Rat	NOAEL 5,000 mg/kg	
Dimethacrylate (EGDMA)	Inhalation	respiratory irritation	May cause respiratory irritation	official classification	NOAEL Not available	

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Silane treated ceramic	Inhalation	pulmonary fibrosis	Not classified	similar compounds	NOAEL Not available	
Polymeric acid	Ingestion	endocrine system | hematopoietic system | liver	Not classified	Rat	NOAEL 200 mg/kg/day	28 days
Polymeric acid	Ingestion	heart | bone, teeth, nails, and/or hair | immune system | muscles | nervous system | eyes | kidney and/or bladder | respiratory system | vascular system	Not classified	Rat	NOAEL 2,000 mg/kg/day	28 days
BHT	Ingestion	liver	Some positive data exist, but the data are not sufficient for classification	Rat	NOAEL 250 mg/kg/day	28 days
BHT	Ingestion	kidney and/or bladder	Not classified	Rat	NOAEL 500 mg/kg/day	2 generation

BHT	Ingestion	blood	Not classified	Rat	LOAEL 420 mg/kg/day	40 days
BHT	Ingestion	endocrine system	Not classified	Rat	NOAEL 25 mg/kg/day	2 generation
BHT	Ingestion	heart	Not classified	Mouse	NOAEL 3,480 mg/kg/day	10 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 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
Silane treated ceramic	444758-98-9		Data not available or insufficient for classification			N/A
Methacrylate (HEMA)	868-77-9	Turbot	Analogous Compound	96 hours	LC50	833 mg/l
Methacrylate (HEMA)	868-77-9	Fathead minnow	Experimental	96 hours	LC50	227 mg/l
Methacrylate (HEMA)	868-77-9	Green algae	Experimental	72 hours	EC50	710 mg/l
Methacrylate (HEMA)	868-77-9	Water flea	Experimental	48 hours	EC50	380 mg/l
Methacrylate (HEMA)	868-77-9	Green algae	Experimental	72 hours	NOEC	160 mg/l
Methacrylate (HEMA)	868-77-9	Water flea	Experimental	21 days	NOEC	24.1 mg/l
Methacrylate (HEMA)	868-77-9		Experimental	16 hours	EC0	>3,000 mg/l
Methacrylate (HEMA)	868-77-9		Experimental	18 hours	LD50	<98 mg per kg of bodyweight
Polymeric acid	25948-33-8		Data not available or insufficient for classification			N/A
Dimethacrylate	931-227-1	Guppy	Experimental	96 hours	LC50	43.2 mg/l
Persulfate	7727-21-1	Algae or other aquatic plants	Estimated	72 hours	EC50	320 mg/l
Persulfate	7727-21-1	Copepod	Estimated	48 hours	LC50	21.22 mg/l
Persulfate	7727-21-1	Rainbow trout	Estimated	96 hours	LC50	76.3 mg/l

Persulfate	7727-21-1	Algae or other aquatic plants	Estimated	72 hours	NOEC	32 mg/l
Potassium salt	7778-77-0	Activated sludge	Estimated	3 hours	NOEC	1,000 mg/l
Potassium salt	7778-77-0	Green algae	Estimated	72 hours	EC50	>100 mg/l
Potassium salt	7778-77-0	Rainbow trout	Estimated	96 hours	LC50	>100 mg/l
Potassium salt	7778-77-0	Water flea	Estimated	48 hours	EC50	>100 mg/l
Potassium salt	7778-77-0	Green algae	Estimated	72 hours	NOEC	100 mg/l
BHT	128-37-0	Activated sludge	Experimental	3 hours	EC50	>10,000 mg/l
BHT	128-37-0	Green algae	Experimental	72 hours	EC50	>0.4 mg/l
BHT	128-37-0	Water flea	Experimental	48 hours	EC50	0.48 mg/l
BHT	128-37-0	Zebra Fish	Experimental	96 hours	No tox obs at lmt of water sol	>100 mg/l
BHT	128-37-0	Green algae	Experimental	72 hours	EC10	0.4 mg/l
BHT	128-37-0	Medaka	Experimental	42 days	NOEC	0.053 mg/l
BHT	128-37-0	Water flea	Experimental	21 days	NOEC	0.023 mg/l
Dimethacrylate (EGDMA)	97-90-5	Activated sludge	Experimental	3 hours	EC50	570 mg/l
Dimethacrylate (EGDMA)	97-90-5	Green algae	Experimental	72 hours	EC50	17.3 mg/l
Dimethacrylate (EGDMA)	97-90-5	Water flea	Experimental	48 hours	EC50	44.9 mg/l
Dimethacrylate (EGDMA)	97-90-5	Zebra Fish	Experimental	96 hours	LC50	15.95 mg/l
Dimethacrylate (EGDMA)	97-90-5	Water flea	Experimental	21 days	NOEC	5.05 mg/l

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Silane treated ceramic	444758-98-9	Data not availbl-insufficient	N/A	N/A	N/A	N/A
Methacrylate (HEMA)	868-77-9	Experimental Hydrolysis		Hydrolytic half-life basic pH	10.9 days (t 1/2)	OECD 111 Hydrolysis func of pH
Methacrylate (HEMA)	868-77-9	Experimental Biodegradation	28 days	BOD	84 %BOD/COD	OECD 301D - Closed bottle test
Polymeric acid	25948-33-8	Data not availbl-insufficient	N/A	N/A	N/A	N/A
Dimethacrylate	931-227-1	Experimental Biodegradation	28 days	BOD	84 %BOD/ThBOD	OECD 301F - Manometric respirometry
Persulfate	7727-21-1	Data not availbl-insufficient	N/A	N/A	N/A	N/A
Potassium salt	7778-77-0	Data not availbl-insufficient	N/A	N/A	N/A	N/A
BHT	128-37-0	Data not availbl-insufficient	N/A	N/A	N/A	N/A
Dimethacrylate (EGDMA)	97-90-5	Experimental Biodegradation	28 days	BOD	71.2 %BOD/ThBOD	Non-standard method

12.3 : Bioaccumulative potential

Material	Cas No.	Test type	Duration	Study Type	Test result	Protocol
Silane treated ceramic	444758-98-9	Data not available or insufficient for classification	N/A	N/A	N/A	N/A

Methacrylate (HEMA)	868-77-9	Experimental Bioconcentration		Log Kow	0.42	OECD 107 log Kow shke flsk mtd
Polymeric acid	25948-33-8	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Dimethacrylate	931-227-1	Estimated Bioconcentration		Log Kow	2.05	Non-standard method
Persulfate	7727-21-1	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Potassium salt	7778-77-0	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
BHT	128-37-0	Experimental BCF - Carp	56 days	Bioaccumulation factor	1277	OECD 305E - Bioaccumulation flow-through fish test
Dimethacrylate (EGDMA)	97-90-5	Experimental Bioconcentration		Log Kow	1.22	Non-standard method

12.4. Mobility in soil

Material	Cas No.	Test type	Study Type	Test result	Protocol
Methacrylate (HEMA)	868-77-9	Experimental Mobility in Soil	Koc	42.7 l/kg	

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)
180106* Chemicals consisting of or containing dangerous substances.

SECTION 14: Transportation information

	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

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

H272	May intensify fire; oxidiser.
H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.

H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

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