



Safety Information Sheet for Medical Devices

Copyright, 2025, Solventum All rights reserved. Copying and/or downloading of this information for the purpose of properly utilizing Solventum products is allowed provided that: (1) the information is copied in full with no changes unless prior written agreement is obtained from Solventum, and (2) neither the copy nor the original is resold or otherwise distributed with the intention of earning a profit thereon.

Document group:	24-8565-4	Version number:	3.00
Revision date:	19/11/2025	Supersedes date:	22/09/2023

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

Protemp™ 4 Base Paste

Product Identification Numbers

LE-F100-0544-0

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:	KCI Medical Limited, Building 47, Charnwood Campus, 10 Bakewell Road, Loughborough, Leicestershire, LE11 5RB, United Kingdom
Telephone:	+44 1344 963 418
E Mail:	psops_supportteam@solventum.com
Website:	Solventum.com

1.4. Emergency telephone number

CHEMTREC 1-800-424-9300 OR 1-703-527-3887, Contract number# 1015211

SECTION 2: Hazard identification

2.1. Classification of the substance or mixture

The retained CLP Regulation (EU) No 1272/2008 as amended for Great Britain

This material has been tested for eye damage/irritation and the test results do not meet the criteria for classification.

This product is a medical device as defined in Directive 93/42/EEC (MDD) respectively Regulation SI 2002 No 618, as amended (UK MDR 2002), 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 the retained CLP Regulation (EC) No. 1272/2008, as amended for Great Britain (Article 1, paragraph 5). Although not required, the classification and label information, as

applicable, is provided below.

CLASSIFICATION:

2.2. Label elements

The retained CLP Regulation (EU) No 1272/2008 as amended for Great Britain

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], as amended for GB
Dimethacrylate (BisEMA6)	(EC-No.) 935-411-2	45 - 55	Substance not classified as hazardous
Silane treated silica	(CAS-No.) 2968358-00-9	20 - 30	Substance not classified as hazardous
Silane treated silica	(CAS-No.) 68909-20-6 (EC-No.) 272-697-1	5 - 15	EUH066 STOT RE 2, H373
Methacrylated polyurethane	(CAS-No.) 1101874-33-2	10 - 15	Aquatic Chronic 4, H413

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

For information on ingredient occupational exposure limits or PBT or vPvB status, see sections 8 and 12 of this SIS

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation

Remove person to fresh air. If you feel unwell, get medical attention.

Skin contact

Wash with soap and water. If signs/symptoms develop, get medical attention.

Eye contact

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

Carbon monoxide

Carbon dioxide.

Irritant vapours or gases.

Condition

During combustion.

During combustion.

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.

6.2. Environmental precautions

Not applicable.

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
Silica, amorphous, inhalable dust	68909-20-6	UK HSE	TWA(as respirable dust):2.4 mg/m ³ ;TWA(as inhalable dust):6 mg/m ³	

UK HSE : 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. Paste
Specific Physical Form:	Paste
Colour	Tooth
Odor	Slight Acrylic
Melting point/freezing point	No data available.
Boiling point/boiling range	No data available.
Flammability	Not applicable.
Flammable Limits(LEL)	Not applicable.
Flammable Limits(UEL)	Not applicable.
Flash point	No flash point
Autoignition temperature	No data available.
Relative density	1.3 - 1.4 [Ref Std: WATER=1]
pH	substance/mixture is non-soluble (in water)
Kinematic Viscosity	No data available.
Water solubility	Negligible
Density	1.3 g/cm3 - 1.4 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	No data available.
Percent volatile	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 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 hazard classes as defined in the retained CLP Regulation (EU) No 1272/2008, as amended for Great Britain.**Signs and Symptoms of Exposure**

Based on test data and/or information on the components, this material may produce the following health effects:

Inhalation

May cause additional health effects (see below).

Skin contact

Prolonged or repeated exposure may cause: Dermal Defatting: Signs/symptoms may include localized redness, itching, drying and cracking of skin.

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:**Prolonged or repeated exposure may cause target organ effects:**

Respiratory effects: Signs/symptoms may include cough, shortness of breath, chest tightness, wheezing, increased heart rate, bluish coloured skin (cyanosis), sputum production, changes in lung function tests, and respiratory failure.

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	Dermal		No data available; calculated ATE >5,000 mg/kg
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
Methacrylated polyurethane	Dermal		LD50 estimated to be 2,000 - 5,000 mg/kg
Methacrylated polyurethane	Ingestion	Rat	LD50 > 2,000 mg/kg
Silane treated silica	Ingestion	Rat	LD50 > 2,000 mg/kg
Silane treated silica	Dermal	similar health hazards	LD50 estimated to be > 5,000 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Methacrylated polyurethane	Rabbit	Minimal irritation
Silane treated silica	Rabbit	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
Overall product	Rabbit	Mild irritant
Methacrylated polyurethane	In vitro data	No significant irritation
Silane treated silica	Rabbit	No significant irritation

Skin Sensitisation

Name	Species	Value
Methacrylated polyurethane	Mouse	Not classified
Silane treated silica	Guinea pig	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
Methacrylated polyurethane	In Vitro	Not mutagenic
Silane treated silica	In Vitro	Not mutagenic

Carcinogenicity

For the component/components, either no data is currently available or the data is not sufficient for classification.

Reproductive Toxicity

Reproductive and/or Developmental Effects

Name	Route	Value	Species	Test result	Exposure Duration
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
-----------------------	-----------	--------------------------------------	-----	---------------------	--------------

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	May cause damage to organs though prolonged or repeated exposure	Rat	LOAEL 0.035 mg/l	13 weeks
Silane treated silica	Inhalation	hematopoietic system kidney and/or bladder	Not classified	Rat	NOAEL 0.035 mg/l	13 weeks
Silane treated silica	Ingestion	liver	Not classified	Rat	NOAEL 1,000 mg/kg/day	5 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 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
Dimethacrylate (BisEMA6)	935-411-2	Green algae	Analogous Compound	72 hours	No tox obs at lmt of water sol	>100 mg/l
Dimethacrylate (BisEMA6)	935-411-2	Rainbow trout	Analogous Compound	96 hours	No tox obs at lmt of water sol	>100 mg/l
Dimethacrylate (BisEMA6)	935-411-2	Water flea	Experimental	48 hours	No tox obs at lmt of water sol	>100 mg/l
Dimethacrylate (BisEMA6)	935-411-2	Green algae	Analogous Compound	72 hours	No tox obs at lmt of water sol	100 mg/l
Dimethacrylate (BisEMA6)	935-411-2	Water flea	Analogous Compound	21 days	No tox obs at lmt of water sol	100 mg/l
Dimethacrylate (BisEMA6)	935-411-2	Zebra Fish	Analogous Compound	34 days	No tox obs at lmt of water sol	100 mg/l
Dimethacrylate (BisEMA6)	935-411-2	Activated sludge	Analogous Compound	3 hours	EC50	>1,000 mg/l
Methacrylated polyurethane	1101874-33-2	Green algae	Endpoint not reached	72 hours	EC50	>100 mg/l

Methacrylated polyurethane	1101874-33-2	Water flea	Experimental	48 hours	EC50	>100 mg/l
Silane treated silica	68909-20-6	Green algae	Experimental	72 hours	ErC50	>10,000 mg/l
Silane treated silica	68909-20-6	Water flea	Experimental	24 hours	EC50	>1,000 mg/l
Silane treated silica	68909-20-6	Zebra Fish	Experimental	96 hours	LC50	>10,000 mg/l

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Dimethacrylate (BisEMA6)	935-411-2	Experimental Biodegradation	28 days	BOD	24 %BOD/ThOD	OECD 301D - Closed bottle test
Methacrylated polyurethane	1101874-33-2	Experimental Biodegradation	28 days	BOD	6 %BOD/ThOD	OECD 301F - Manometric respirometry
Silane treated silica	68909-20-6	Data not available - insufficient	N/A	N/A	N/A	N/A

12.3 : Bioaccumulative potential

Material	Cas No.	Test type	Duration	Study Type	Test result	Protocol
Dimethacrylate (BisEMA6)	935-411-2	Modeled Bioconcentration		Bioaccumulation factor	7	Catalogic™
Dimethacrylate (BisEMA6)	935-411-2	Experimental Bioconcentration		Log Kow	≥4.66	OECD 117 log Kow HPLC method
Methacrylated polyurethane	1101874-33-2	Experimental Bioconcentration		Log Kow	7.28	
Silane treated silica	68909-20-6	Data not available or insufficient for classification	N/A	N/A	N/A	N/A

12.4. Mobility in soil

Material	Cas No.	Test type	Study Type	Test result	Protocol
Dimethacrylate (BisEMA6)	935-411-2	Modeled Mobility in Soil	Koc	360-7600 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. Other adverse effects

This material does not contain any substances that are assessed to be an endocrine disruptor for environmental effects

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

Not hazardous for transportation.

	Ground Transport (ADR)	Air Transport (IATA)	Marine Transport (IMDG)
14.1 UN 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 Transport in bulk according to Annex II of Marpol 73/78 and IBC Code	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

Global inventory status

Contact the manufacturer for more information

SECTION 16: Other information

List of relevant H statements

EUH066	Repeated exposure may cause skin dryness or cracking.
H373	May cause damage to organs through prolonged or repeated exposure.
H413	May cause long lasting harmful effects to aquatic life.

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. 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). 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 Solventum 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 Solventum representative listed on the Safety Information Sheet.

Solventum Safety Information Sheets for Great Britain are available at [Solventum.com](https://www.solventum.com)



Safety Information Sheet for Medical Devices

Copyright, 2025, Solventum All rights reserved. Copying and/or downloading of this information for the purpose of properly utilizing Solventum products is allowed provided that: (1) the information is copied in full with no changes unless prior written agreement is obtained from Solventum, and (2) neither the copy nor the original is resold or otherwise distributed with the intention of earning a profit thereon.

Document group: 24-8558-9
Revision date: 22/10/2025

Version number: 2.00
Supersedes date: 31/01/2023

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

Protemp™ 4 Catalyst Paste

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: KCI Medical Limited, Building 47, Charnwood Campus, 10 Bakewell Road, Loughborough, Leicestershire, LE11 5RB, United Kingdom
Telephone: +44 1344 963 418
E Mail: psops_supportteam@solventum.com
Website: Solventum.com

1.4. Emergency telephone number

CHEMTREC 1-800-424-9300 OR 1-703-527-3887, Contract number# 1015211

SECTION 2: Hazard identification

2.1. Classification of the substance or mixture

The retained CLP Regulation (EU) No 1272/2008 as amended for Great Britain

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 SI 2002 No 618, as amended (UK MDR 2002), 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 the retained CLP Regulation (EC) No. 1272/2008, as amended for Great Britain (Article 1, paragraph 5). Although not required, the classification and label information, as applicable, is provided below.

CLASSIFICATION:

Hazardous to the Aquatic Environment (Chronic), Category 3 - Aquatic Chronic 3; H412

For full text of H phrases, see Section 16.

2.2. Label elements

The retained CLP Regulation (EU) No 1272/2008 as amended for Great Britain

HAZARD STATEMENTS:

H412 Harmful to aquatic life with long lasting effects.

SUPPLEMENTAL INFORMATION:**Supplemental Hazard Statements:**

EUH208 Contains Tert-butyl 3,5,5-trimethylperoxyhexanoate. May produce an allergic reaction.

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], as amended for GB
Diacetate	(CAS-No.) 19224-29-4 (EC-No.) 242-895-2	70 - 80	Substance not classified as hazardous
Barbituric acid derivative	(CAS-No.) 72846-00-5 (EC-No.) 276-940-2	5 - 15	Acute Tox. 4, H302 Eye Irrit. 2, H319
Silane treated silica	(CAS-No.) 68909-20-6 (EC-No.) 272-697-1	5 - 15	EUH066 STOT RE 2, H373
Diacetate	None	1 - 10	Substance not classified as hazardous
Perester	(CAS-No.) 13122-18-4 (EC-No.) 236-050-7	< 0.4	Org. Perox. CD, H242 Skin Sens. 1B, H317 Aquatic Acute 1, H400,M=1 Aquatic Chronic 3, H412

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. If symptoms develop, remove the affected person to fresh air. Get medical attention.

Skin contact

Wash with soap and water. If you feel unwell, 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**

Carbon monoxide
Carbon dioxide.
Irritant vapours or gases.

Condition

During combustion.
During combustion.
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
Silica, amorphous, inhalable dust	68909-20-6	UK HSE	TWA(as respirable dust):2.4 mg/m ³ ;TWA(as inhalable dust):6 mg/m ³	

UK HSE : 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	White
Odor	Slight Acidic
Melting point/freezing point	No data available.
Boiling point/boiling range	No data available.
Flammability	Not applicable.
Flammable Limits(LEL)	No data available.
Flammable Limits(UEL)	No data available.
Flash point	No flash point
Autoignition temperature	No data available.
Relative density	1.2 - 1.3 [Ref Std:WATER=1]
pH	substance/mixture is non-soluble (in water)
Kinematic Viscosity	No data available.
Water solubility	Negligible

Density1.2 g/cm³ - 1.3 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***No data available.***Percent volatile***No data available.***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 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 hazard classes as defined in the retained CLP Regulation (EU) No 1272/2008, as amended for Great Britain.**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

May be harmful in contact with skin. 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

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	Dermal		No data available; calculated ATE >2,000 - =5,000 mg/kg
Overall product	Ingestion		No data available; calculated ATE >2,000 - =5,000 mg/kg
Diacetate	Dermal	Professional judgement	LD50 estimated to be 2,000 - 5,000 mg/kg
Diacetate	Ingestion	Rat	LD50 > 2,000 mg/kg
Barbituric acid derivative	Ingestion	Rat	LD50 >300, <2000 mg/kg
Silane treated silica	Ingestion	Rat	LD50 > 2,000 mg/kg
Silane treated silica	Dermal	similar health hazards	LD50 estimated to be > 5,000 mg/kg
Perester	Dermal	Rat	LD50 > 2,000 mg/kg
Perester	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 0.8 mg/l
Perester	Ingestion	Rat	LD50 12,905 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Diacetate	In vitro data	No significant irritation
Barbituric acid derivative	In vitro data	No significant irritation
Silane treated silica	Rabbit	No significant irritation
Perester	Rabbit	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
Diacetate	In vitro data	No significant irritation
Barbituric acid derivative	In vitro data	Severe irritant
Silane treated silica	Rabbit	No significant irritation
Perester	Rabbit	No significant irritation

Skin Sensitisation

Name	Species	Value
Diacetate	Mouse	Not classified
Barbituric acid derivative	Guinea pig	Not classified
Silane treated silica	Guinea	Not classified

	pig	
Perester	Guinea pig	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
Diacetate	In Vitro	Not mutagenic
Barbituric acid derivative	In Vitro	Not mutagenic
Silane treated silica	In Vitro	Not mutagenic

Carcinogenicity

For the component/components, either no data is currently available or the data is not sufficient for classification.

Reproductive Toxicity

Reproductive and/or Developmental Effects

Name	Route	Value	Species	Test result	Exposure Duration
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

Target Organ(s)

Specific Target Organ Toxicity - single exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Barbituric acid derivative	Inhalation	respiratory irritation	Some positive data exist, but the data are not sufficient for classification	similar health hazards	NOAEL Not available	

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Silane treated silica	Inhalation	respiratory system	May cause damage to organs though prolonged or repeated exposure	Rat	LOAEL 0.035 mg/l	13 weeks
Silane treated silica	Inhalation	hematopoietic system kidney and/or bladder	Not classified	Rat	NOAEL 0.035 mg/l	13 weeks
Silane treated silica	Ingestion	liver	Not classified	Rat	NOAEL 1,000 mg/kg/day	5 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 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
Diacetate	19224-29-4	Green algae	Experimental	72 hours	EC50	>100 mg/l
Diacetate	19224-29-4	Green algae	Experimental	72 hours	NOEC	100 mg/l
Barbituric acid derivative	72846-00-5	N/A	Data not available or insufficient for classification	N/A	N/A	N/A
Silane treated silica	68909-20-6	Green algae	Experimental	72 hours	ErC50	>10,000 mg/l
Silane treated silica	68909-20-6	Water flea	Experimental	24 hours	EC50	>1,000 mg/l
Silane treated silica	68909-20-6	Zebra Fish	Experimental	96 hours	LC50	>10,000 mg/l
Perester	13122-18-4	Green algae	Experimental	72 hours	ErC50	0.51 mg/l
Perester	13122-18-4	Rainbow trout	Experimental	96 hours	LC50	7.03 mg/l
Perester	13122-18-4	Water flea	Experimental	48 hours	EC50	>100 mg/l
Perester	13122-18-4	Green algae	Experimental	72 hours	NOEC	0.125 mg/l
Perester	13122-18-4	Water flea	Experimental	21 days	NOEC	0.22 mg/l
Perester	13122-18-4	Activated sludge	Experimental	3 hours	EC50	327.02 mg/l

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Diacetate	19224-29-4	Experimental Biodegradation	28 days	CO2 evolution	8-13 %CO2 evolution/THCO2 evolution	OECD 301B - Modified sturm or CO2
Barbituric acid derivative	72846-00-5	Experimental Biodegradation	28 days	CO2 evolution	29.1 %CO2 evolution/THCO2 evolution	OECD 301B - Modified sturm or CO2
Barbituric acid derivative	72846-00-5	Estimated Photolysis		Photolytic half-life (in air)	1.48 days (t 1/2)	
Silane treated silica	68909-20-6	Data not availbl-insufficient	N/A	N/A	N/A	N/A
Perester	13122-18-4	Experimental Biodegradation	28 days	BOD	72 %BOD/ThOD	OECD 301D - Closed bottle test
Perester	13122-18-4	Experimental Aquatic Inherent Biodegrad.	56 days	BOD	58 %BOD/ThOD	OECD 302A - Modified SCAS Test
Perester	13122-18-4	Experimental Hydrolysis		Hydrolytic half-life (pH 7)	51 hours (t 1/2)	OECD 111 Hydrolysis func of pH

12.3 : Bioaccumulative potential

Material	Cas No.	Test type	Duration	Study Type	Test result	Protocol
----------	---------	-----------	----------	------------	-------------	----------

Diacetate	19224-29-4	Estimated Bioconcentration		Log Kow	7.16	
Barbituric acid derivative	72846-00-5	Experimental Bioconcentration		Log Kow	2.57	
Silane treated silica	68909-20-6	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Perester	13122-18-4	Modeled Bioconcentration		Bioaccumulation factor	380	Catalogic™
Perester	13122-18-4	Experimental Bioconcentration		Log Kow	5.16	OECD 117 log Kow HPLC method

12.4. Mobility in soil

Material	Cas No.	Test type	Study Type	Test result	Protocol
Barbituric acid derivative	72846-00-5	Estimated Mobility in Soil	Koc	<270 l/kg	ACD/Labs ChemSketch™
Perester	13122-18-4	Modeled Mobility in Soil	Koc	3,550 l/kg	Episuite™

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

This material does not contain any substances that are assessed to be an endocrine disruptor for environmental effects

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

Not hazardous for transportation.

ADR/IMDG/IATA: Not restricted for transport.

	Ground Transport (ADR)	Air Transport (IATA)	Marine Transport (IMDG)
14.1 UN 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	No data available.	No data available.	No data available.

hazards			
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 Transport in bulk according to Annex II of Marpol 73/78 and IBC Code	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

Global inventory status

Contact the manufacturer for more information

SECTION 16: Other information

List of relevant H statements

EUH066	Repeated exposure may cause skin dryness or cracking.
H242	Heating may cause a fire.
H302	Harmful if swallowed.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H373	May cause damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
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. 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). 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 Solventum 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 Solventum representative listed on the Safety Information Sheet.

Solventum Safety Information Sheets for Great Britain are available at [Solventum.com](https://www.solventum.com)