Safety Information Sheet for Medical Devices

Document group:	28-0649-5	**Version number:**	2.00
Revision date:	10/11/2025	**Supersedes date:**	25/10/2019

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
Filtek™ Z500 Universal Restorative (8020, 8021)

Product Identification Numbers

70-2010-7852-7	70-2010-7853-5	70-2010-7854-3	70-2010-7855-0	70-2010-7856-8
70-2010-7857-6	70-2010-7858-4	70-2010-7859-2	70-2010-7860-0	70-2010-7862-6
70-2010-7863-4	70-2010-7864-2	70-2010-7865-9	70-2010-7866-7	70-2010-7867-5
70-2010-7868-3	70-2010-7869-1	70-2010-7871-7	70-2010-7872-5	70-2010-7873-3
UU-0131-9786-6	UU-0131-9787-4	UU-0131-9788-2	UU-0131-9789-0	UU-0131-9790-8
UU-0131-9791-6	UU-0131-9792-4	UU-0131-9793-2	UU-0131-9794-0	UU-0131-9795-7
UU-0131-9796-5	UU-0131-9797-3	UU-0131-9798-1	UU-0131-9799-9	UU-0131-9800-5
UU-0131-9803-9				

7000054510	7000054491	7000054492	7000054493	7000054494
7000054495	7000054496	7000054497	7000054498	7000054499
7000054501	7000054502	7000054503	7000054512	7000054504
7000054505	7000054506	7000054507	7000054508	7000054511
7100342410	7100342211	7100342212	7100342403	7100342404
7100342405	7100342406	7100342407	7100342190	7100342191
7100342192	7100342247	7100342243	7100342244	7100342245
7100342246				

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

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

SIGNAL WORD
WARNING.

Symbols
GHS07 (Exclamation mark) |

Pictograms

HAZARD STATEMENTS:

H317	May cause an allergic skin reaction.

PRECAUTIONARY STATEMENTS

Prevention:

P280E	Wear protective gloves.

Contains 84% of components with unknown hazards to the aquatic environment.

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
Silane treated ceramic	(CAS-No.) 444758-98-9	60 - 100	Substance not classified as hazardous
Silane treated silica	(CAS-No.) 248596-91-0	1 - 10	Substance not classified as hazardous
Urethane dimethacrylate (UDMA)	(CAS-No.) 72869-86-4 (EC-No.) 276-957-5	5 - 10	Skin Sens. 1B, H317 Aquatic Chronic 3, H412
Dimethacrylate (BIS-MEPP)	(CAS-No.) 41637-38-1 (EC-No.) 609-946-4	5 - 10	Substance not classified as hazardous
Carbosilane surfactant	(EC-No.) 701-308-4	5 - 10	Substance not classified as hazardous
Triethyleneglycol dimenthacrylate (TEGDMA)	(CAS-No.) 109-16-0 (EC-No.) 203-652-6	< 5	Skin Sens. 1B, H317
Iodonium salt	(CAS-No.) 58109-40-3 (EC-No.) 261-134-5	< 0.2	Acute Tox. 2, H300 Aquatic Chronic 2, H411

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

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
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
No occupational exposure limit values exist for any of the components listed in Section 3 of this SIS.

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	Tooth
Odor	Slight Acrylate
Melting point/freezing point	*No data available.*
Boiling point/boiling range	*Not applicable.*
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	1.9 [*Ref Std:*WATER=1]
pH	*substance/mixture is non-soluble (in water)*
Kinematic Viscosity	*Not applicable.*
Water solubility	Negligible
Density	1.9 g/cm3

9.2. Other information

9.2.2 Other safety characteristics

EU Volatile Organic Compounds	*No data available.*
Evaporation rate	*Not applicable.*
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
Light.

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
Respiratory tract irritation: Signs/symptoms may include cough, sneezing, nasal discharge, headache, hoarseness, and nose and throat pain.

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
May be harmful if swallowed.
May cause additional health effects (see below).

Additional Health Effects:

Reproductive/Developmental Toxicity:
Contains a chemical or chemicals which can cause birth defects or other reproductive harm.

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 >2,000 - =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
Silane treated silica	Dermal		LD50 estimated to be > 5,000 mg/kg

Silane treated silica	Ingestion		LD50 estimated to be > 5,000 mg/kg
Dimethacrylate (BIS-MEPP)	Dermal	Rat	LD50 > 2,000 mg/kg
Dimethacrylate (BIS-MEPP)	Ingestion	Rat	LD50 > 2,000 mg/kg
Urethane dimethacrylate (UDMA)	Dermal	Rat	LD50 > 2,000 mg/kg
Urethane dimethacrylate (UDMA)	Ingestion	Rat	LD50 > 5,000 mg/kg
Carbosilane surfactant	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Carbosilane surfactant	Ingestion	Rat	LD50 > 11,700 mg/kg
Triethyleneglycol dimenthacrylate (TEGDMA)	Dermal	Mouse	LD50 > 2,000
Triethyleneglycol dimenthacrylate (TEGDMA)	Ingestion	Rat	LD50 10,837 mg/kg
Iodonium salt	Ingestion	Rat	LD50 32 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Silane treated ceramic	similar compounds	No significant irritation
Silane treated silica	Professional judgement	No significant irritation
Dimethacrylate (BIS-MEPP)	In vitro data	No significant irritation
Urethane dimethacrylate (UDMA)	Rabbit	No significant irritation
Carbosilane surfactant	Rabbit	No significant irritation
Triethyleneglycol dimenthacrylate (TEGDMA)	Rabbit	No significant irritation
Iodonium salt	Rabbit	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
Silane treated ceramic	similar compounds	Mild irritant
Silane treated silica	Professional judgement	No significant irritation
Dimethacrylate (BIS-MEPP)	In vitro data	No significant irritation
Urethane dimethacrylate (UDMA)	Rabbit	No significant irritation
Carbosilane surfactant	In vitro data	No significant irritation
Triethyleneglycol dimenthacrylate (TEGDMA)	Rabbit	No significant irritation
Iodonium salt	Rabbit	Mild irritant

Skin Sensitisation

Name	Species	Value
Silane treated ceramic	similar compounds	Not classified
Dimethacrylate (BIS-MEPP)	Multiple animal species	Not classified
Urethane dimethacrylate (UDMA)	Multiple animal species	Sensitising
Carbosilane surfactant	Mouse	Not classified

Triethyleneglycol dimenthacrylate (TEGDMA)	Mouse	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
Dimethacrylate (BIS-MEPP)	In Vitro	Not mutagenic
Urethane dimethacrylate (UDMA)	In Vitro	Not mutagenic
Carbosilane surfactant	In Vitro	Not mutagenic
Triethyleneglycol dimenthacrylate (TEGDMA)	In Vitro	Some positive data exist, but the data are not sufficient for classification
Iodonium salt	In Vitro	Some positive data exist, but the data are not sufficient for classification

Carcinogenicity

Name	Route	Species	Value
Silane treated ceramic	Inhalation	similar compounds	Some positive data exist, but the data are not sufficient for classification
Triethyleneglycol dimenthacrylate (TEGDMA)	Dermal	Mouse	Not carcinogenic

Reproductive Toxicity

Reproductive and/or Developmental Effects

Name	Route	Value	Species	Test result	Exposure Duration
Dimethacrylate (BIS-MEPP)	Ingestion	Not classified for female reproduction	Rat	NOAEL 1,000 mg/kg/day	premating into lactation
Dimethacrylate (BIS-MEPP)	Ingestion	Not classified for male reproduction	Rat	NOAEL 1,000 mg/kg/day	28 days
Dimethacrylate (BIS-MEPP)	Ingestion	Not classified for development	Rat	NOAEL 1,000 mg/kg/day	during gestation
Urethane dimethacrylate (UDMA)	Ingestion	Not classified for female reproduction	Rat	NOAEL 1,000 mg/kg/day	premating into lactation
Urethane dimethacrylate (UDMA)	Ingestion	Not classified for male reproduction	Rat	NOAEL 1,000 mg/kg/day	56 days
Urethane dimethacrylate (UDMA)	Ingestion	Not classified for development	Rat	NOAEL 1,000 mg/kg/day	premating into lactation
Carbosilane surfactant	Ingestion	Not classified for development	Rat	NOAEL 1,000 mg/kg/day	during gestation
Triethyleneglycol dimenthacrylate (TEGDMA)	Ingestion	Not classified for female reproduction	Rat	NOAEL 1,000 mg/kg/day	premating into lactation
Triethyleneglycol dimenthacrylate (TEGDMA)	Ingestion	Not classified for male reproduction	Rat	NOAEL 1,000 mg/kg/day	5 weeks
Triethyleneglycol dimenthacrylate (TEGDMA)	Ingestion	Not classified for development	Rat	NOAEL 1,000 mg/kg/day	premating into lactation

Target Organ(s)

Specific Target Organ Toxicity - single exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure

						Duration
Iodonium salt	Inhalation	respiratory irritation	Not classified	Not available	Irritation Equivocal	

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	
Dimethacrylate (BIS-MEPP)	Ingestion	hematopoietic system | liver | immune system | kidney and/or bladder | endocrine system | eyes	Not classified	Rat	NOAEL 1,000 mg/kg/day	13 weeks
Urethane dimethacrylate (UDMA)	Ingestion	liver | kidney and/or bladder | heart | skin | endocrine system | gastrointestinal tract | bone, teeth, nails, and/or hair | hematopoietic system | immune system | muscles | nervous system | eyes | respiratory system | vascular system	Not classified	Rat	NOAEL 1,000 mg/kg/day	56 days
Carbosilane surfactant	Ingestion	endocrine system | hematopoietic system | liver | heart | skin | gastrointestinal tract | bone, teeth, nails, and/or hair | immune system | muscles | nervous system | eyes | kidney and/or bladder | respiratory system | vascular system	Not classified	Rat	NOAEL 1,000 mg/kg/day	90 days
Triethyleneglycol dimenthacrylate (TEGDMA)	Dermal	liver	Not classified	Mouse	NOAEL 2,000 mg/kg/day	13 weeks
Triethyleneglycol dimenthacrylate (TEGDMA)	Dermal	skin	Not classified	Mouse	NOAEL 100 mg/kg/day	13 weeks
Triethyleneglycol dimenthacrylate (TEGDMA)	Dermal	gastrointestinal tract | hematopoietic system | nervous system | kidney and/or bladder | respiratory system	Not classified	Mouse	NOAEL 2,000 mg/kg/day	13 weeks
Triethyleneglycol dimenthacrylate (TEGDMA)	Ingestion	hematopoietic system | liver | nervous system | kidney and/or bladder | eyes	Not classified	Rat	NOAEL 3,849 mg/kg/day	13 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
Silane treated ceramic	444758-98-9	N/A	Data not available or insufficient for classification	N/A	N/A	N/A
Carbosilane surfactant	701-308-4	Green algae	Endpoint not reached	96 hours	EC50	>100 mg/l
Carbosilane surfactant	701-308-4	Green algae	Experimental	96 hours	EC10	1.1 mg/l
Carbosilane surfactant	701-308-4	Activated sludge	Experimental	3 hours	EC50	>100 mg/l
Dimethacrylate (BIS-MEPP)	41637-38-1	Green algae	Analogous Compound	72 hours	No tox obs at lmt of water sol	>100 mg/l
Dimethacrylate (BIS-MEPP)	41637-38-1	Rainbow trout	Analogous Compound	96 hours	No tox obs at lmt of water sol	>100 mg/l
Dimethacrylate (BIS-MEPP)	41637-38-1	Water flea	Experimental	48 hours	No tox obs at lmt of water sol	>100 mg/l
Dimethacrylate (BIS-MEPP)	41637-38-1	Green algae	Analogous Compound	72 hours	No tox obs at lmt of water sol	100 mg/l
Dimethacrylate (BIS-MEPP)	41637-38-1	Water flea	Analogous Compound	21 days	No tox obs at lmt of water sol	100 mg/l
Dimethacrylate (BIS-MEPP)	41637-38-1	Zebra Fish	Analogous Compound	34 days	No tox obs at lmt of water sol	100 mg/l
Dimethacrylate (BIS-MEPP)	41637-38-1	Activated sludge	Experimental	3 hours	EC50	>1,000 mg/l
Silane treated silica	248596-91-0	N/A	Data not available or insufficient for classification	N/A	N/A	N/A
Urethane dimethacrylate (UDMA)	72869-86-4	Green algae	Endpoint not reached	72 hours	ErC50	>100 mg/l
Urethane dimethacrylate (UDMA)	72869-86-4	Water flea	Experimental	48 hours	EC50	>100 mg/l
Urethane dimethacrylate (UDMA)	72869-86-4	Zebra Fish	Experimental	96 hours	LC50	10.1 mg/l
Urethane dimethacrylate (UDMA)	72869-86-4	Green algae	Endpoint not reached	72 hours	ErC10	>100 mg/l
Triethyleneglycol dimenthacrylate (TEGDMA)	109-16-0	Green algae	Experimental	72 hours	ErC50	>100 mg/l
Triethyleneglycol dimenthacrylate (TEGDMA)	109-16-0	Zebra Fish	Experimental	96 hours	LC50	16.4 mg/l
Triethyleneglycol dimenthacrylate	109-16-0	Green algae	Experimental	72 hours	NOEC	18.6 mg/l

(TEGDMA)						
Triethyleneglycol dimenthacrylate (TEGDMA)	109-16-0	Water flea	Experimental	21 days	NOEC	32 mg/l
Iodonium salt	58109-40-3	Water flea	Experimental	48 hours	EC50	9.5 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
Carbosilane surfactant	701-308-4	Experimental Biodegradation	28 days	BOD	21 %BOD/ThOD	similar to OECD 301F
Carbosilane surfactant	701-308-4	Experimental Hydrolysis		Hydrolytic half-life (pH 7)	29 days (t 1/2)	
Dimethacrylate (BIS-MEPP)	41637-38-1	Experimental Biodegradation	28 days	BOD	24 %BOD/ThOD	OECD 301D - Closed bottle test
Silane treated silica	248596-91-0	Data not availbl-insufficient	N/A	N/A	N/A	N/A
Urethane dimethacrylate (UDMA)	72869-86-4	Experimental Biodegradation	28 days	CO2 evolution	22 %CO2 evolution/THCO2 evolution (does not pass 10-day window)	OECD 301B - Modified sturm or CO2
Triethyleneglycol dimenthacrylate (TEGDMA)	109-16-0	Experimental Biodegradation	28 days	CO2 evolution	85 %CO2 evolution/THCO2 evolution	OECD 301B - Modified sturm or CO2
Iodonium salt	58109-40-3	Data not availbl-insufficient	N/A	N/A	N/A	N/A

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
Carbosilane surfactant	701-308-4	Modeled Bioconcentration		Bioaccumulation factor	292.4	Episuite™
Carbosilane surfactant	701-308-4	Experimental Bioconcentration		Log Kow	4.63	OECD 117 log Kow HPLC method
Dimethacrylate (BIS-MEPP)	41637-38-1	Modeled Bioconcentration		Bioaccumulation factor	7	Catalogic™
Dimethacrylate (BIS-MEPP)	41637-38-1	Experimental Bioconcentration		Log Kow	≥4.66	OECD 117 log Kow HPLC method
Silane treated silica	248596-91-0	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Urethane dimethacrylate (UDMA)	72869-86-4	Experimental Bioconcentration		Log Kow	3.39	
Triethyleneglycol dimenthacrylate (TEGDMA)	109-16-0	Experimental Bioconcentration		Log Kow	2.3	EC A.8 Partition Coefficient
Iodonium salt	58109-40-3	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
Carbosilane surfactant	701-308-4	Experimental Mobility in Soil	Koc	24,000 l/kg	OECD 121 Estim. of Koc by HPLC

Dimethacrylate (BIS-MEPP)	41637-38-1	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.

EU waste code (product container after use)
180107 Chemicals other than those mentioned in 18 01 06

SECTION 14: Transportation information

Not hazardous for transportation.

ADR/IATA/IMDG: Not hazardous 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 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

H300	Fatal if swallowed.
H317	May cause an allergic skin reaction.
H411	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. 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