



Safety Information Sheet for Medical Devices

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Document group:	34-6746-1	Version number:	2.00
Revision date:	11/06/2025	Supersedes date:	05/12/2024

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™ Cavilon™ Advanced Skin Protectant 5050, 5050G, 5050G4P, 5051, 5051G, 5051C, 5051GP, 5051G4P

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses

Medical device; refer to Instructions for Use

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:

Flammable Liquid, Category 2 - Flam. Liq. 2; H225

Serious Eye Damage/Eye Irritation, Category 2 - Eye Irrit. 2; H319
Hazardous to the Aquatic Environment (Acute), Category 1 - Aquatic Acute 1; H400
Hazardous to the Aquatic Environment (Chronic), Category 2 - Aquatic Chronic 2; H411

This product is a medical device as defined in Directive 93/42/EEC (MDD), which is invasive or used in direct physical contact with the human body and therefore is exempt from the requirements of classification and labelling according to the retained CLP Regulation (EC) No. 1272/2008, as amended for Great Britain (Article 1, paragraph 5).

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

Not applicable

SIGNAL WORD

DANGER.

Symbols

GHS02 (Flame) |GHS07 (Exclamation mark) |GHS09 (Environment) |

Pictograms



HAZARD STATEMENTS:

H225	Highly flammable liquid and vapour.
H319	Causes serious eye irritation.
H400	Very toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.

PRECAUTIONARY STATEMENTS

Prevention:

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P273	Avoid release to the environment.

Response:

P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P391	Collect spillage.

7% of the mixture consists of components of unknown acute oral toxicity.

Contains 7% 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
Hexamethyldisiloxane	(CAS-No.) 107-46-0 (EC-No.) 203-492-7	80 - 90	Aquatic Acute 1, H400,M=1 Aquatic Chronic 2, H411 Flam. Liq. 2, H225
Acrylic Polymer	Trade Secret	5 - 10	Substance not classified as hazardous
2-Octyl Cyanoacrylate	(CAS-No.) 133978-15-1 (EC-No.) 700-845-1	5 - 10	Substance not classified as hazardous

Please see section 16 for the full text of any H statements referred to in this section

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

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation

No need for first aid is anticipated. If symptoms develop, remove the affected person to fresh air. Get medical attention.

Skin contact

Wash with soap and water. 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

Do not induce vomiting. 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 flammable liquids such as dry chemical or carbon dioxide to extinguish.

5.2. Special hazards arising from the substance or mixture

Closed containers exposed to heat from fire may build pressure and explode.

Hazardous Decomposition or By-Products

Substance

Carbon monoxide
Carbon dioxide.

Condition

During combustion.
During combustion.

5.3. Advice for fire-fighters

Water may not effectively extinguish fire; however, it should be used to keep fire-exposed containers and surfaces cool and prevent explosive rupture. 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. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Use only non-sparking tools. 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. Warning! A motor could be an ignition source and could cause flammable gases or vapours in the spill area to burn or explode. 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. For larger spills, cover drains and build dykes to prevent entry into sewer systems or bodies of water.

6.3. Methods and material for containment and cleaning up

Contain spill. Working from around the edges of the spill inward, cover with bentonite, vermiculite, or commercially available inorganic absorbent material. Mix in sufficient absorbent until it appears dry. Remember, adding an absorbent material does not remove a physical, health, or environmental hazard. Collect as much of the spilled material as possible using non-sparking tools. Place in a metal container approved for transportation by appropriate authorities. Clean up residue with an appropriate solvent selected by a qualified and authorized person. Ventilate the area with fresh air. Read and follow safety precautions on the solvent label and SIS. 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 explosion-proof ventilation equipment.

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:

Indirect vented goggles.

Applicable Norms/Standards

Use eye protection conforming to EN 166

Skin/hand protection

No chemical protective gloves are required.

Respiratory protection

None required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Liquid.
Colour	Colourless
Odor	Mild Alcohol
Melting point/freezing point	-59 °C
Boiling point/boiling range	101 °C
Flammability	Flammable Liquid: Category 2.
Flammable Limits(LEL)	0.5 %
Flammable Limits(UEL)	21.8 %
Flash point	-8.3 °C [<i>Test Method:</i> Closed Cup]
Autoignition temperature	<i>Not applicable.</i>
Relative density	0.77
pH	
Kinematic Viscosity	<i>Not applicable.</i>
Water solubility	<i>Not applicable.</i>
Density	0.77 g/ml

9.2. Other information

9.2.2 Other safety characteristics

EU Volatile Organic Compounds	<i>No data available.</i>
Evaporation rate	<i>Not applicable.</i>
Molecular weight	<i>Not applicable.</i>

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

Sparks and/or flames.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

<u>Substance</u>	<u>Condition</u>
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

No health effects are expected.

Skin contact

Contact with the skin during product use is not expected to result in significant irritation.

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	Ingestion		No data available; calculated ATE >5,000 mg/kg
Hexamethyldisiloxane	Dermal	Rabbit	LD50 12,160 mg/kg
Hexamethyldisiloxane	Inhalation-Vapour (4 hours)	Rat	LC50 106 mg/l
Hexamethyldisiloxane	Ingestion	Rat	LD50 > 12,200 mg/kg
2-Octyl Cyanoacrylate	Ingestion	similar compounds	LD50 > 5,000 mg/kg
2-Octyl Cyanoacrylate	Dermal	similar health hazards	LD50 estimated to be > 5,000 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Overall product	Rabbit	No significant irritation
Hexamethyldisiloxane	Rabbit	No significant irritation
2-Octyl Cyanoacrylate	Rabbit	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
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Overall product	In vitro data	Severe irritant
Hexamethyldisiloxane	Rabbit	Mild irritant
2-Octyl Cyanoacrylate	similar compounds	No significant irritation

Skin Sensitisation

Name	Species	Value
Overall product	Human	Not classified
Hexamethyldisiloxane	Human	Not classified
2-Octyl Cyanoacrylate	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
Hexamethyldisiloxane	In Vitro	Not mutagenic
Hexamethyldisiloxane	In vivo	Not mutagenic
2-Octyl Cyanoacrylate	In Vitro	Not mutagenic

Carcinogenicity

Name	Route	Species	Value
Hexamethyldisiloxane	Inhalation	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
Hexamethyldisiloxane	Inhalation	Not classified for female reproduction	Rabbit	NOAEL 33 mg/l	2 generation
Hexamethyldisiloxane	Inhalation	Not classified for male reproduction	Rabbit	NOAEL 33 mg/l	2 generation
Hexamethyldisiloxane	Inhalation	Not classified for development	Multiple animal species	NOAEL 19.9 mg/l	during gestation

Target Organ(s)

Specific Target Organ Toxicity - single exposure

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

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Overall product	Dermal	heart skin endocrine system bone, teeth, nails, and/or hair hematopoietic system liver immune system muscles nervous system kidney and/or bladder	Not classified	Rat	NOAEL 63 mg/cm2/day	90 days

		respiratory system vascular system				
Hexamethyldisiloxane	Dermal	liver kidney and/or bladder endocrine system hematopoietic system nervous system	Not classified	Rat	NOAEL 1,000 mg/kg/day	4 weeks
Hexamethyldisiloxane	Inhalation	hematopoietic system	Not classified	Rat	NOAEL 33 mg/l	13 weeks
Hexamethyldisiloxane	Inhalation	kidney and/or bladder	Not classified	Rat	NOAEL 1.3 mg/l	13 weeks
Hexamethyldisiloxane	Inhalation	heart endocrine system liver immune system nervous system eyes respiratory system	Not classified	Rat	NOAEL 33 mg/l	13 weeks
Hexamethyldisiloxane	Ingestion	hematopoietic system liver immune system nervous system kidney and/or bladder	Not classified	Rat	NOAEL 640 mg/kg/day	4 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
Hexamethyldisiloxane	107-46-0	Green algae	Experimental	70 hours	ErC50	>0.55 mg/l
Hexamethyldisiloxane	107-46-0	Rainbow trout	Experimental	96 hours	LC50	0.46 mg/l
Hexamethyldisiloxane	107-46-0	Green algae	Experimental	70 hours	ErC10	0.09 mg/l
Hexamethyldisiloxane	107-46-0	Water flea	Experimental	21 days	NOEC	0.08 mg/l
2-Octyl Cyanoacrylate	133978-15-1	N/A	Data not available or insufficient for classification	N/A	N/A	N/A

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Hexamethyldisiloxane	107-46-0	Experimental Photolysis		Photolytic half-life (in air)	22.5 days (t 1/2)	
Hexamethyldisiloxane	107-46-0	Experimental Hydrolysis		Hydrolytic half-life (pH 7)	120 hours (t 1/2)	
2-Octyl Cyanoacrylate	133978-15-1	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
Hexamethyldisiloxane	107-46-0	Experimental BCF - Fish	56 days	Bioaccumulation factor	2410	OECD305-Bioconcentration
Hexamethyldisiloxane	107-46-0	Experimental Bioconcentration		Log Kow	4.2	
2-Octyl Cyanoacrylate	133978-15-1	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
Hexamethyldisiloxane	107-46-0	Modeled Mobility in Soil	Koc	4,400 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.

	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

H225	Highly flammable liquid and vapour.
H319	Causes serious eye irritation.
H400	Very toxic to aquatic life.
H411	Toxic 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