



## Safety Information Sheet for Medical Devices

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

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

3M™ Polyether Adhesive - New Formulation

#### Product Identification Numbers

70-2011-4442-8

7100059327

#### 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

<b>Address:</b>	3M United Kingdom PLC, 3M Centre, Cain Road, Bracknell, Berkshire, RG12 8HT.
<b>Telephone:</b>	+44 (0)1344 858 000
<b>E Mail:</b>	tox.uk@mmm.com
<b>Website:</b>	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

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:**

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

Serious Eye Damage/Eye Irritation, Category 2 - Eye Irrit. 2; H319

Specific Target Organ Toxicity-Single Exposure, Category 3 - STOT SE 3; H336

For full text of H phrases, see Section 16.

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

DANGER.

**Symbols:**

GHS02 (Flame) |GHS07 (Exclamation mark) |

**Pictograms****Ingredients:**

Ingredient	CAS Nbr	EC No.	% by Wt
Ethyl acetate	141-78-6	205-500-4	40 - 70

**HAZARD STATEMENTS:**

H225	Highly flammable liquid and vapour.
H319	Causes serious eye irritation.
H336	May cause drowsiness or dizziness.

**PRECAUTIONARY STATEMENTS****Prevention:**

P210A	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P261A	Avoid breathing vapours.

**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.
P370 + P378G	In case of fire: Use a fire fighting agent suitable for flammable liquids such as dry chemical or carbon dioxide to extinguish.

**SUPPLEMENTAL INFORMATION:****Supplemental Hazard Statements:**

EUH066	Repeated exposure may cause skin dryness or cracking.
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**2.3. Other hazards**

For information on hazards and safe use, please consider the corresponding sections of this document.

**SECTION 3: Composition/information on ingredients**

Ingredient	CAS Nbr	EC No.	% by Wt	Classification
Ethyl acetate	141-78-6	205-500-4	40 - 70	Flam. Liq. 2, H225; Eye Irrit. 2, H319; STOT SE 3, H336; EUH066
Silicon resin	68440-70-0		40 - 60	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**

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. Do not induce vomiting. Get immediate 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.

**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.

### 6.3. Methods and material for containment and cleaning up

Contain spill. Cover spill area with a fire-extinguishing foam. 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

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
Ethyl acetate	141-78-6	UK HSC	TWA:734 mg/m <sup>3</sup> (200 ppm);STEL:1468 mg/m <sup>3</sup> (400 ppm)	

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

<b>Appearance</b>	
<b>Physical state</b>	Liquid.
<b>Colour</b>	Red
<b>Specific Physical Form:</b>	Viscous.
<b>Odor</b>	Characteristic Organic solvent
<b>pH</b>	<i>No data available.</i>
<b>Boiling point/boiling range</b>	76.1 °C
<b>Melting point</b>	<i>No data available.</i>
<b>Flammability (solid, gas)</b>	Not applicable.
<b>Explosive properties</b>	Not classified
<b>Oxidising properties</b>	Not classified
<b>Flash point</b>	-3.9 °C [ <i>Test Method: Closed Cup</i> ]
<b>Autoignition temperature</b>	<i>No data available.</i>
<b>Flammable Limits(LEL)</b>	1.2 %
<b>Flammable Limits(UEL)</b>	11.5 %
<b>Relative density</b>	> 0.9 [ <i>Ref Std: WATER=1</i> ]
<b>Water solubility</b>	Nil
<b>Viscosity</b>	approximately 0.25 Pa-s
<b>Density</b>	approximately 0.9 g/cm <sup>3</sup>

### 9.2. Other information

<b>EU Volatile Organic Compounds</b>	<i>No data available.</i>
<b>Molecular weight</b>	<i>No data available.</i>
<b>Percent volatile</b>	<i>No data available.</i>

## 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

Sparks and/or flames.

Heat.

### 10.5 Incompatible materials

None known.

### 10.6 Hazardous decomposition products

<u>Substance</u>	<u>Condition</u>
Carbon monoxide	Oxidation, heat or reaction
Carbon dioxide.	Oxidation, heat or reaction

## SECTION 11: Toxicological information

The information below may not agree with the EU material classification in Section 2 and/or the ingredient

classifications in Section 3 if specific ingredient classifications are mandated by a competent authority. In addition, statements and data presented in Section 11 are based on UN GHS calculation rules and classifications derived from 3M assessments.

### 11.1 Information on Toxicological effects

#### Signs and Symptoms of Exposure

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

#### Inhalation

Respiratory tract irritation: Signs/symptoms may include cough, sneezing, nasal discharge, headache, hoarseness, and nose and throat pain. May cause additional health effects (see below).

#### Skin contact

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

#### Eye contact

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

#### Ingestion

Gastrointestinal irritation: Signs/symptoms may include abdominal pain, stomach upset, nausea, vomiting and diarrhoea. May cause additional health effects (see below).

#### Additional Health Effects:

#### Single exposure may cause target organ effects:

Central nervous system (CNS) depression: Signs/symptoms may include headache, dizziness, drowsiness, incoordination, nausea, slowed reaction time, slurred speech, giddiness, and unconsciousness.

#### 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
Ethyl acetate	Dermal	Rabbit	LD50 > 18,000 mg/kg
Ethyl acetate	Inhalation-Vapour (4 hours)	Rat	LC50 70.5 mg/l
Ethyl acetate	Ingestion	Rat	LD50 5,620 mg/kg

ATE = acute toxicity estimate

#### Skin Corrosion/Irritation

Name	Species	Value
Ethyl acetate	Rabbit	Minimal irritation

#### Serious Eye Damage/Irritation

Name	Species	Value
Ethyl acetate	Rabbit	Mild irritant

#### Skin Sensitisation

Name	Species	Value
Ethyl acetate	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
Ethyl acetate	In Vitro	Not mutagenic
Ethyl acetate	In vivo	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**

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

**Target Organ(s)****Specific Target Organ Toxicity - single exposure**

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Ethyl acetate	Inhalation	central nervous system depression	May cause drowsiness or dizziness	Human	NOAEL Not available	
Ethyl acetate	Inhalation	respiratory irritation	Some positive data exist, but the data are not sufficient for classification	Human	NOAEL Not available	
Ethyl acetate	Ingestion	central nervous system depression	May cause drowsiness or dizziness	Human	NOAEL Not available	

**Specific Target Organ Toxicity - repeated exposure**

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Ethyl acetate	Inhalation	endocrine system   liver   nervous system	Not classified	Rat	NOAEL 0.043 mg/l	90 days
Ethyl acetate	Inhalation	hematopoietic system	Not classified	Rabbit	LOAEL 16 mg/l	40 days
Ethyl acetate	Ingestion	hematopoietic system   liver   kidney and/or bladder	Not classified	Rat	NOAEL 3,600 mg/kg/day	90 days

**Aspiration Hazard**

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

**Please contact the address or phone number listed on the first page of the SIS for additional toxicological information on this material and/or its components.**

The product was evaluated by a toxicologist to be safe for its intended use.

**SECTION 12: Ecological information**

The information below may not agree with the EU material classification in Section 2 and/or the ingredient classifications in Section 3 if specific ingredient classifications are mandated by a competent authority. In addition, statements and data presented in Section 12 are based on UN GHS calculation rules and classifications derived from 3M assessments.

**12.1. Toxicity**

No product test data available.

Material	CAS #	Organism	Type	Exposure	Test endpoint	Test result
Ethyl acetate	141-78-6	Crustacea	Experimental	48 hours	EC50	165 mg/l
Ethyl acetate	141-78-6	Fish	Experimental	96 hours	LC50	212.5 mg/l
Ethyl acetate	141-78-6	Green Algae	Experimental	72 hours	NOEC	>100 mg/l
Ethyl acetate	141-78-6	Water flea	Experimental	21 days	NOEC	2.4 mg/l
Silicon resin	68440-70-0		Data not available or insufficient for classification			

## 12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Ethyl acetate	141-78-6	Experimental Photolysis		Photolytic half-life (in air)	20.0 days (t 1/2)	Other methods
Ethyl acetate	141-78-6	Experimental Biodegradation	14 days	BOD	94 % BOD/ThBOD	OECD 301C - MITI test (I)
Silicon resin	68440-70-0	Data not availbl-insufficient			N/A	

## 12.3 : Bioaccumulative potential

Material	Cas No.	Test type	Duration	Study Type	Test result	Protocol
Ethyl acetate	141-78-6	Experimental Bioconcentration		Log Kow	0.68	Other methods
Silicon resin	68440-70-0	Data not available or insufficient for classification	N/A	N/A	N/A	N/A

## 12.4. Mobility in soil

Please contact manufacturer for more details

## 12.5. Results of the PBT and vPvB assessment

This material does not contain any substances that are assessed to be a PBT or vPvB

## 12.6. Other adverse effects

No information available.

# SECTION 13: Disposal considerations

## 13.1 Waste treatment methods

Dispose of contents/ container in accordance with the local/regional/national/international regulations.

Refer to Instructions for Use (IFU) for more information.

## EU waste code (product as sold)

180106\* Chemicals consisting of or containing dangerous substances.

# SECTION 14: Transportation information

# 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.
H225	Highly flammable liquid and vapour.
H319	Causes serious eye irritation.
H336	May cause drowsiness or dizziness.

**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](http://www.3M.com/uk)**