



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™ RELYX™ LUTING CEMENT LIQUID (3505L, 3515L)

Product Identification Numbers

70-2010-2502-3	70-2010-2674-0	70-2010-2698-9	70-2010-3120-3
7000054230	7100111748	7100111792	7100111794

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

Identified uses

Medical device; refer to Instructions for Use

Restrictions on Use

For use only by dental professionals

1.3 Details of the supplier of the safety information sheet for medical devices

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

1.4. Emergency telephone number

+44 (0)1344 858 000

SECTION 2: Hazard identification

2.1. Classification of the substance or mixture

CLP REGULATION (EC) No 1272/2008

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:

Serious Eye Damage/Eye Irritation, Category 2 - Eye Irrit. 2; H319
Skin Corrosion/Irritation, Category 2 - Skin Irrit. 2; H315
Skin Sensitization, Category 1 - Skin Sens. 1; H317

For full text of H phrases, see Section 16.

2.2. Label elements

CLP REGULATION (EC) No 1272/2008

SIGNAL WORD

WARNING.

Symbols:

GHS07 (Exclamation mark) |

Pictograms



Ingredients:

Ingredient	CAS Nbr	EC No.	% by Wt
Methacrylate (HEMA)	868-77-9	212-782-2	25 - 35

HAZARD STATEMENTS:

H319	Causes serious eye irritation.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.

PRECAUTIONARY STATEMENTS

Prevention:

P280E	Wear protective gloves.
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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.
P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.

2.3. Other hazards

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

SECTION 3: Composition/information on ingredients
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Ingredient	CAS Nbr	EC No.	% by Wt	Classification
Water	7732-18-5	231-791-2	30 - 40	Substance not classified as hazardous
Polymeric acid	25948-33-8		30 - 40	Substance not classified as hazardous
Methacrylate (HEMA) (REACH Reg.	868-77-9	212-782-2	25 - 35	Skin Irrit. 2, H315; Eye Irrit. 2, H319;

No.:01-2119490169-29)				Skin Sens. 1, H317 - Nota D
Ethyl acetate	141-78-6	205-500-4	< 2	Flam. Liq. 2, H225; Eye Irrit. 2, H319; STOT SE 3, H336; EUH066

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

Carbon monoxide
Carbon dioxide.

Condition

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

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. Place in a closed container approved for transportation by appropriate authorities. Clean up residue with water. 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 ³ (200 ppm);STEL:1468 mg/m ³ (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

Appearance	
Physical state	Liquid.
Colour	Transparent Yellow
Specific Physical Form:	Liquid.
Odor	Slight Odor, Sweet Odor
pH	2.2 - 3.2
Boiling point/boiling range	No data available.
Melting point	Not applicable.
Flammability (solid, gas)	Not applicable.
Explosive properties	Not classified
Oxidising properties	Not classified
Flash point	104 °C [Test Method: Tagliabue closed cup]
Autoignition temperature	No data available.
Flammable Limits(LEL)	Not applicable.
Flammable Limits(UEL)	Not applicable.
Relative density	1.2 [Ref Std: WATER=1]
Water solubility	Complete
Viscosity	175 - 225 mm ² /sec
Density	1.2 g/ml

9.2. Other information

EU Volatile Organic Compounds	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

None known.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

Substance

None known.

Condition

Refer to section 5.2 for hazardous decomposition products during combustion.

SECTION 11: Toxicological information

The information below may not agree with the EU material classification in Section 2 and/or the ingredient classifications in Section 3 if specific ingredient classifications are mandated by a competent authority. In addition, statements and data presented in Section 11 are based on UN GHS calculation rules and classifications derived from 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.

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

Moderate eye irritation: Signs/symptoms may include redness, swelling, pain, tearing, and blurred or hazy 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
Polymeric acid	Ingestion	Rat	LD50 > 5,000 mg/kg
Polymeric acid	Dermal	similar health hazards	LD50 estimated to be > 5,000 mg/kg
Methacrylate (HEMA)	Dermal	Rabbit	LD50 > 5,000 mg/kg
Methacrylate (HEMA)	Ingestion	Rat	LD50 5,564 mg/kg
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
Methacrylate (HEMA)	Rabbit	Minimal irritation
Ethyl acetate	Rabbit	Minimal irritation

Serious Eye Damage/Irritation

Name	Species	Value
Methacrylate (HEMA)	Rabbit	Moderate irritant
Ethyl acetate	Rabbit	Mild irritant

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Skin Sensitisation

Name	Species	Value
Methacrylate (HEMA)	Human and animal	Sensitising
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
Methacrylate (HEMA)	In vivo	Not mutagenic
Methacrylate (HEMA)	In Vitro	Some positive data exist, but the data are not sufficient for classification
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**

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

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

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Polymeric acid	Ingestion	nervous system	Not classified	Rat	NOAEL 5,000 mg/kg	
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
Polymeric acid	Ingestion	endocrine system hematopoietic system liver	Not classified	Rat	NOAEL 200 mg/kg/day	28 days
Polymeric acid	Ingestion	heart bone, teeth, nails, and/or hair immune system muscles nervous system eyes kidney and/or bladder respiratory system vascular system	Not classified	Rat	NOAEL 2,000 mg/kg/day	28 days
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
Polymeric acid	25948-33-8		Data not available or insufficient for classification			
Methacrylate (HEMA)	868-77-9	Fathead minnow	Experimental	96 hours	LC50	227 mg/l
Methacrylate (HEMA)	868-77-9	Green algae	Experimental	72 hours	EC50	710 mg/l
Methacrylate (HEMA)	868-77-9	Water flea	Experimental	48 hours	EC50	380 mg/l
Methacrylate (HEMA)	868-77-9	Green Algae	Experimental	72 hours	NOEC	160 mg/l
Methacrylate (HEMA)	868-77-9	Water flea	Experimental	21 days	NOEC	24.1 mg/l
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

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Polymeric acid	25948-33-8	Data not available or insufficient			N/A	
Methacrylate (HEMA)	868-77-9	Experimental Biodegradation	14 days	BOD	95 % BOD/ThBOD	OECD 301C - MITI test (I)
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)

12.3 : Bioaccumulative potential

Material	Cas No.	Test type	Duration	Study Type	Test result	Protocol
Polymeric acid	25948-33-8	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Methacrylate (HEMA)	868-77-9	Experimental Bioconcentration		Log Kow	0.42	Other methods

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Ethyl acetate	141-78-6	Experimental Bioconcentration		Log Kow	0.68	Other methods
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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

70-2010-2502-3, 70-2010-2674-0, 70-2010-2698-9, 70-2010-3120-3

Not hazardous for transportation

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.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
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