



## 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™ ESPE™ VITREBOND™ PLUS LINER LIQUID B

#### Product Identification Numbers

LE-F100-0224-3      LE-F100-0224-4      LE-F100-0684-9

#### 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), 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
Hydroxyethyl Methacrylate (HEMA)	868-77-9	212-782-2	15 - 25

### 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.

#### 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

Ingredient	CAS Nbr	EC No.	% by Wt	Classification
Polymeric acid	25948-33-8		40 - 50	Substance not classified as hazardous
Water	7732-18-5	231-791-2	30 - 40	Substance not classified as hazardous
Hydroxyethyl Methacrylate (HEMA) (REACH Reg. No.:01-2119490169-29)	868-77-9	212-782-2	15 - 25	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317 - Nota D

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Ethylacetate	141-78-6	205-500-4	< 5	Flam. Liq. 2, H225; Eye Irrit. 2, H319; STOT SE 3, H336; EUH066
Initiator	58109-40-3	261-134-5	< 1	Acute Tox. 2, H300
Tetrahydrofuran (THF)	109-99-9	203-726-8	< 0.2	Flam. Liq. 2, H225; EUH019; Eye Irrit. 2, H319; Carc. 2, H351; STOT SE 3, H335

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

<u>Substance</u>	<u>Condition</u>
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. 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
Tetrahydrofuran (THF)	109-99-9	UK HSC	TWA: 150 mg/m <sup>3</sup> (50 ppm); STEL: 300 mg/m <sup>3</sup> (100 ppm)	SKIN
Ethylacetate	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

#### Appearance

Physical state

Liquid.

Colour

Yellow

Specific Physical Form:

Liquid.

Odor

Slight Acrylate

pH

2.5

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

> 101.1 °C [Test Method:Closed Cup]

Autoignition temperature

*Not applicable.*

Flammable Limits(LEL)

*Not applicable.*

Flammable Limits(UEL)

*Not applicable.*

Relative density

1.14 [Ref Std:WATER=1]

Water solubility

Complete

Viscosity

200 - 300 mm<sup>2</sup>/sec

Density

1.14 g/ml

### 9.2. Other information

EU Volatile Organic Compounds

*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 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. 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

May be harmful if swallowed.

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

#### Additional Health Effects:

#### Carcinogenicity:

Contains a chemical or chemicals which can cause cancer.

#### 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	Ingestion		No data available; calculated ATE 2,000 - 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
Hydroxyethyl Methacrylate (HEMA)	Dermal	Rabbit	LD50 > 5,000 mg/kg
Hydroxyethyl Methacrylate (HEMA)	Ingestion	Rat	LD50 5,564 mg/kg
Ethylacetate	Dermal	Rabbit	LD50 > 18,000 mg/kg
Ethylacetate	Inhalation-Vapour (4 hours)	Rat	LC50 70.5 mg/l
Ethylacetate	Ingestion	Rat	LD50 5,620 mg/kg
Initiator	Ingestion	Rat	LD50 32 mg/kg
Tetrahydrofuran (THF)	Dermal	Rat	LD50 > 2,000 mg/kg
Tetrahydrofuran (THF)	Inhalation-	Rat	LC50 54 mg/l

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	Vapour (4 hours)		
Tetrahydrofuran (THF)	Ingestion	Rat	LD50 3,180 mg/kg

ATE = acute toxicity estimate

**Skin Corrosion/Irritation**

Name	Species	Value
Hydroxyethyl Methacrylate (HEMA)	Rabbit	Minimal irritation
Ethylacetate	Rabbit	Minimal irritation
Initiator	Rabbit	No significant irritation
Tetrahydrofuran (THF)	Rabbit	Minimal irritation

**Serious Eye Damage/Irritation**

Name	Species	Value
Hydroxyethyl Methacrylate (HEMA)	Rabbit	Moderate irritant
Ethylacetate	Rabbit	Mild irritant
Initiator	Rabbit	Mild irritant
Tetrahydrofuran (THF)	Rabbit	Corrosive

**Skin Sensitisation**

Name	Species	Value
Hydroxyethyl Methacrylate (HEMA)	Human and animal	Sensitising
Ethylacetate	Guinea pig	Not classified
Tetrahydrofuran (THF)	Human and animal	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
Hydroxyethyl Methacrylate (HEMA)	In vivo	Not mutagenic
Hydroxyethyl Methacrylate (HEMA)	In Vitro	Some positive data exist, but the data are not sufficient for classification
Ethylacetate	In Vitro	Not mutagenic
Ethylacetate	In vivo	Not mutagenic
Initiator	In Vitro	Some positive data exist, but the data are not sufficient for classification
Tetrahydrofuran (THF)	In Vitro	Not mutagenic
Tetrahydrofuran (THF)	In vivo	Not mutagenic

**Carcinogenicity**

Name	Route	Species	Value
Tetrahydrofuran (THF)	Inhalation	Multiple animal species	Carcinogenic.

**Reproductive Toxicity**

**Reproductive and/or Developmental Effects**

Name	Route	Value	Species	Test result	Exposure Duration
Hydroxyethyl Methacrylate (HEMA)	Ingestion	Not classified for female reproduction	Rat	NOAEL 1,000	premating & during

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				mg/kg/day	gestation
Hydroxyethyl Methacrylate (HEMA)	Ingestion	Not classified for male reproduction	Rat	NOAEL 1,000 mg/kg/day	49 days
Hydroxyethyl Methacrylate (HEMA)	Ingestion	Not classified for development	Rat	NOAEL 1,000 mg/kg/day	prematuring & during gestation
Tetrahydrofuran (THF)	Ingestion	Not classified for female reproduction	Rat	NOAEL 782 mg/kg/day	2 generation
Tetrahydrofuran (THF)	Ingestion	Not classified for male reproduction	Rat	NOAEL 782 mg/kg/day	2 generation
Tetrahydrofuran (THF)	Ingestion	Not classified for development	Rat	NOAEL 305 mg/kg/day	2 generation
Tetrahydrofuran (THF)	Inhalation	Not classified for development	Mouse	NOAEL 1.8 mg/l	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	
Ethylacetate	Inhalation	central nervous system depression	May cause drowsiness or dizziness	Human	NOAEL Not available	
Ethylacetate	Inhalation	respiratory irritation	Some positive data exist, but the data are not sufficient for classification	Human	NOAEL Not available	
Ethylacetate	Ingestion	central nervous system depression	May cause drowsiness or dizziness	Human	NOAEL Not available	
Initiator	Inhalation	respiratory irritation	Not classified	Not available	Irritation Equivocal	
Tetrahydrofuran (THF)	Inhalation	central nervous system depression	May cause drowsiness or dizziness	Human	NOAEL Not available	
Tetrahydrofuran (THF)	Inhalation	respiratory irritation	May cause respiratory irritation		NOAEL Not available	
Tetrahydrofuran (THF)	Inhalation	respiratory system	Not classified	Rabbit	NOAEL 2.9 mg/l	4 hours
Tetrahydrofuran (THF)	Ingestion	central nervous system depression	May cause drowsiness or dizziness	Rat	NOAEL 180 mg/kg	not applicable

**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
Ethylacetate	Inhalation	endocrine system   liver   nervous system	Not classified	Rat	NOAEL 0.043 mg/l	90 days
Ethylacetate	Inhalation	hematopoietic system	Not classified	Rabbit	LOAEL 16 mg/l	40 days
Ethylacetate	Ingestion	hematopoietic system   liver   kidney and/or bladder	Not classified	Rat	NOAEL 3,600 mg/kg/day	90 days
Tetrahydrofuran (THF)	Inhalation	liver	Some positive data exist, but the	Rat	NOAEL 0.6	12 weeks



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			data are not sufficient for classification		mg/l	
Tetrahydrofuran (THF)	Inhalation	respiratory system	Not classified	Rat	NOAEL 2.9 mg/l	12 weeks
Tetrahydrofuran (THF)	Inhalation	kidney and/or bladder	Not classified	Rat	NOAEL 0.6 mg/l	105 weeks
Tetrahydrofuran (THF)	Ingestion	liver	Some positive data exist, but the data are not sufficient for classification	Rat	NOAEL Not available	2 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.

**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			
Hydroxyethyl Methacrylate (HEMA)	868-77-9	Fathead minnow	Experimental	96 hours	LC50	227 mg/l
Hydroxyethyl Methacrylate (HEMA)	868-77-9	Green algae	Experimental	72 hours	EC50	710 mg/l
Hydroxyethyl Methacrylate (HEMA)	868-77-9	Water flea	Experimental	48 hours	EC50	380 mg/l
Hydroxyethyl Methacrylate (HEMA)	868-77-9	Green Algae	Experimental	72 hours	NOEC	160 mg/l
Hydroxyethyl Methacrylate (HEMA)	868-77-9	Water flea	Experimental	21 days	NOEC	24.1 mg/l
Ethylacetate	141-78-6	Crustacea	Experimental	48 hours	EC50	165 mg/l
Ethylacetate	141-78-6	Fish	Experimental	96 hours	LC50	212.5 mg/l
Ethylacetate	141-78-6	Green Algae	Experimental	72 hours	NOEC	>100 mg/l
Ethylacetate	141-78-6	Water flea	Experimental	21 days	NOEC	2.4 mg/l
Initiator	58109-40-3	Water flea	Experimental	48 hours	EC50	9.5 mg/l
Tetrahydrofuran (THF)	109-99-9	Fathead minnow	Experimental	96 hours	LC50	2,160 mg/l
Tetrahydrofuran (THF)	109-99-9	Water flea	Experimental	48 hours	LC50	3,485 mg/l
Tetrahydrofuran (THF)	109-99-9	Fathead minnow	Experimental	33 days	NOEC	216 mg/l

**12.2. Persistence and degradability**

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Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Polymeric acid	25948-33-8	Data not availbl- insufficient			N/A	
Hydroxylethyl Methacrylate (HEMA)	868-77-9	Experimental Biodegradation	14 days	BOD	95 % BOD/ThBOD	OECD 301C - MITI test (I)
Ethylacetate	141-78-6	Experimental Photolysis		Photolytic half-life (in air)	20.0 days (t 1/2)	Other methods
Ethylacetate	141-78-6	Experimental Biodegradation	14 days	BOD	94 % BOD/ThBOD	OECD 301C - MITI test (I)
Initiator	58109-40-3	Data not availbl- insufficient			N/A	
Tetrahydrofuran (THF)	109-99-9	Experimental Biodegradation	28 days	BOD	39 % BOD/ThBOD	Other methods

### 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
Hydroxylethyl Methacrylate (HEMA)	868-77-9	Experimental Bioconcentration		Log Kow	0.42	Other methods
Ethylacetate	141-78-6	Experimental Bioconcentration		Log Kow	0.68	Other methods
Initiator	58109-40-3	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Tetrahydrofuran (THF)	109-99-9	Experimental Bioconcentration		Log Kow	0.45	Other methods

### 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

ADR/IATA/IMDG: Not restricted for transport.

## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

**Carcinogenicity**

Contact the manufacturer for more information

**Global inventory status**

Contact the manufacturer for more information

**SECTION 16: Other information**

**List of relevant H statements**

EUH019	May form explosive peroxides.
EUH066	Repeated exposure may cause skin dryness or cracking.
H225	Highly flammable liquid and vapour.
H300	Fatal if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H336	May cause drowsiness or dizziness.
H351	Suspected of causing cancer.

**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)**