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™ Unitek™ Transbond™ XT Primer (712-034)

Product Identification Numbers
70-2020-8946-5

7000004380

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:	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:

Skin Sensitization, Category 1B - Skin Sens. 1B; 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
Dimethacrylate (Bis-GMA)	1565-94-2	216-367-7	45 - 55
Triethylene glycol dimethacrylate	109-16-0	203-652-6	45 - 55

HAZARD STATEMENTS:

H317	May cause an allergic skin reaction.

PRECAUTIONARY STATEMENTS

Prevention:

P280E	Wear protective gloves.

Response:

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
Dimethacrylate (Bis-GMA)	1565-94-2	216-367-7	45 - 55	Substance not classified as hazardous
Triethylene glycol dimethacrylate (REACH Reg. No.:01-2119969287-21)	109-16-0	203-652-6	45 - 55	Skin Sens. 1, H317
Triphenylantimony	603-36-1	210-037-6	< 1	Acute Tox. 4, H332 - Nota 1,A Acute Tox. 3, H301
Aromatic amine	50438-75-0		< 0.5	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335
Stabilizer	123-31-9	204-617-8	< 0.1	Acute Tox. 4, H302; Eye Dam. 1,

				H318; Skin Sens. 1B, H317; Muta. 2, H341; Carc. 2, H351; Aquatic Acute 1, H400,M=10

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. 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 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
Stabilizer	123-31-9	UK HSC	TWA: 0.5 mg/m³	
Antimony trioxide	603-36-1	UK HSC	TWA(as Sb):0.5 mg/m3	

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
Odor	Slight Acrylate
pH	*Not applicable.*
Boiling point/boiling range	*Not applicable.*
Melting point	*Not applicable.*
Flammability (solid, gas)	Not applicable.
Explosive properties	Not classified
Oxidising properties	Not classified
Flash point	> 104.4 ºC [*Test Method:*Closed Cup] [*Details:*Polymerizes]
Autoignition temperature	*No data available.*
Flammable Limits(LEL)	*Not applicable.*
Flammable Limits(UEL)	*Not applicable.*
Relative density	1.14 [*Ref Std:*WATER=1]
Water solubility	Nil
Viscosity	175 mm²/sec [@ 23 ºC]
Density	1.14 g/ml [*Ref Std:*WATER=1]

9.2. Other information

EU Volatile Organic Compounds	*No data available.*
Molecular weight	*No data available.*
Percent volatile	Nil

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 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
This product may have a characteristic odour; however, no adverse health effects are anticipated.

Skin contact
Mild Skin Irritation: Signs/symptoms may include localised redness, swelling, itching, and dryness. 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	Dermal		No data available; calculated ATE >5,000 mg/kg
Overall product	Ingestion		No data available; calculated ATE >5,000 mg/kg
Triethylene glycol dimethacrylate	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Triethylene glycol dimethacrylate	Ingestion	Rat	LD50 10,837 mg/kg
Dimethacrylate (Bis-GMA)	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Dimethacrylate (Bis-GMA)	Ingestion	Rat	LD50 > 11,700 mg/kg
Triphenylantimony	Inhalation-Dust/Mist		LC50 estimated to be 1 - 5 mg/l
Triphenylantimony	Dermal	Rat	LD50 > 2,000 mg/kg
Triphenylantimony	Ingestion	Rat	LD50 82.5 mg/kg
Stabilizer	Dermal	Rat	LD50 > 4,800 mg/kg
Stabilizer	Ingestion	Rat	LD50 302 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Triethylene glycol dimethacrylate	Guinea pig	Mild irritant
Dimethacrylate (Bis-GMA)	Rabbit	No significant irritation
Triphenylantimony	Rabbit	Minimal irritation
Stabilizer	Human and animal	Minimal irritation

Serious Eye Damage/Irritation

Name	Species	Value
Triethylene glycol dimethacrylate	Professional judgement	Moderate irritant
Dimethacrylate (Bis-GMA)	In vitro data	No significant irritation
Triphenylantimony	Rabbit	Mild irritant
Stabilizer	Human	Corrosive

Skin Sensitisation

Name	Species	Value
Triethylene glycol dimethacrylate	Human and animal	Sensitising
Dimethacrylate (Bis-GMA)	Mouse	Not classified
Stabilizer	Guinea pig	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
Triethylene glycol dimethacrylate	In Vitro	Some positive data exist, but the data are not sufficient for classification
Dimethacrylate (Bis-GMA)	In Vitro	Not mutagenic
Stabilizer	In Vitro	Some positive data exist, but the data are not sufficient for classification
Stabilizer	In vivo	Some positive data exist, but the data are not sufficient for classification

Carcinogenicity

Name	Route	Species	Value
Triethylene glycol dimethacrylate	Dermal	Mouse	Not carcinogenic
Stabilizer	Dermal	Mouse	Not carcinogenic
Stabilizer	Ingestion	Multiple animal species	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
Triethylene glycol dimethacrylate	Ingestion	Not classified for female reproduction	Mouse	NOAEL 1 mg/kg/day	1 generation
Triethylene glycol dimethacrylate	Ingestion	Not classified for male reproduction	Mouse	NOAEL 1 mg/kg/day	1 generation
Triethylene glycol dimethacrylate	Ingestion	Not classified for development	Mouse	NOAEL 1 mg/kg/day	1 generation
Dimethacrylate (Bis-GMA)	Ingestion	Not classified for development	Rat	NOAEL 1,000 mg/kg/day	during gestation
Stabilizer	Ingestion	Not classified for female reproduction	Rat	NOAEL 150 mg/kg/day	2 generation
Stabilizer	Ingestion	Not classified for male reproduction	Rat	NOAEL 150 mg/kg/day	2 generation
Stabilizer	Ingestion	Not classified for development	Rat	NOAEL 100 mg/kg/day	during organogenesis

Target Organ(s)

Specific Target Organ Toxicity - single exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Stabilizer	Ingestion	nervous system	May cause damage to organs	Rat	NOAEL Not available	not applicable

Stabilizer	Ingestion	kidney and/or bladder	Not classified	Rat	NOAEL 400 mg/kg	not applicable

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Triethylene glycol dimethacrylate	Dermal	kidney and/or bladder | blood	Not classified	Mouse	NOAEL 833 mg/kg/day	78 weeks
Dimethacrylate (Bis-GMA)	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
Stabilizer	Ingestion	blood	Not classified	Rat	NOAEL Not available	40 days
Stabilizer	Ingestion	bone marrow | liver	Not classified	Rat	NOAEL Not available	9 weeks
Stabilizer	Ingestion	kidney and/or bladder	Not classified	Rat	LOAEL 50 mg/kg/day	15 months
Stabilizer	Ocular	eyes	Not classified	Human	NOAEL Not available	occupational exposure

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
Dimethacrylate (Bis-GMA)	1565-94-2		Data not available or insufficient for classification			
Triethylene glycol dimethacrylate	109-16-0	Zebra Fish	Experimental	96 hours	LC50	16.4 mg/l
Triethylene glycol dimethacrylate	109-16-0	Green Algae	Experimental	72 hours	EC50	>100 mg/l
Triethylene glycol dimethacrylate	109-16-0	Green algae	Experimental	72 hours	NOEC	18.6 mg/l
Triethylene glycol dimethacrylate	109-16-0	Water flea	Experimental	21 days	NOEC	32 mg/l
Triphenylantimony	603-36-1		Data not available or insufficient for classification			
Aromatic amine	50438-75-0		Data not available or insufficient for classification			
Stabilizer	123-31-9	Water flea	Experimental	48 hours	EC50	0.061 mg/l

Stabilizer	123-31-9	Rainbow trout	Experimental	96 hours	LC50	0.044 mg/l
Stabilizer	123-31-9	Green algae	Experimental	72 hours	EC50	0.053 mg/l
Stabilizer	123-31-9	Fathead minnow	Experimental	32 days	NOEC	>=0.066 mg/l
Stabilizer	123-31-9	Water flea	Experimental	21 days	NOEC	0.0029 mg/l
Stabilizer	123-31-9	Green Algae	Experimental	72 hours	NOEC	0.0015 mg/l

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Dimethacrylate (Bis-GMA)	1565-94-2	Estimated Biodegradation	28 days	BOD	32 % weight	OECD 301C - MITI test (I)
Triethylene glycol dimethacrylate	109-16-0	Experimental Biodegradation	28 days	CO2 evolution	85 % weight	OECD 301B - Modified sturm or CO2
Triphenylantimony	603-36-1	Estimated Biodegradation	28 days	BOD	<20 % weight	OECD 301F - Manometric respirometry
Aromatic amine	50438-75-0	Estimated Biodegradation	28 days	BOD	7 % weight	OECD 301C - MITI test (I)
Stabilizer	123-31-9	Experimental Biodegradation	14 days	BOD	70 % BOD/ThBOD	OECD 301C - MITI test (I)

12.3 : Bioaccumulative potential

Material	Cas No.	Test type	Duration	Study Type	Test result	Protocol
Dimethacrylate (Bis-GMA)	1565-94-2	Estimated Bioconcentration		Bioaccumulation factor	5.8	Estimated: Bioconcentration factor
Triethylene glycol dimethacrylate	109-16-0	Experimental Bioconcentration		Log Kow	2.3	Other methods
Triphenylantimony	603-36-1	Estimated Bioconcentration		Log Kow	6.02	Estimated: Octanol-water partition coefficient
Aromatic amine	50438-75-0	Estimated Bioconcentration		Bioaccumulation factor	3.6	Estimated: Bioconcentration factor
Stabilizer	123-31-9	Experimental Bioconcentration		Log Kow	0.59	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

70-2020-8946-5

Not hazardous for transportation

ADR/IMDG/IATA: 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

H301	Toxic if swallowed.
H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H341	Suspected of causing genetic defects.
H351	Suspected of causing cancer.
H400	Very toxic to aquatic life.

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