



TruLock® Light Activated Bonding Resin

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

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

1.1. Product identifier

Product form : Mixture
Product name : TruLock® Light Activated Bonding resin

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

1.2.1. Relevant identified uses

Use of the substance/mixture : Orthodontic bonding resin

1.2.2. Uses advised against

Use of the substance/mixture : None

1.3. Details of the supplier of the safety data sheet

Manufacturer/Importer/Representative/User/Distributor: RMO 2165 Earlywood Drive Franklin, IN 46131 USA SRN #: US-MF-00003482 T 1 800 525 6735 customerservice@rmortho.com https://rmortho.com/	FDA Registration: According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations FDA Registration: 1718476
Australian Sponsor: AB Orthodontics PTY LTD 13/15 Collins St Melbourne VIC 3000 Australia T +61 3 9650 2526	EC Representative: RMO Europe 300 rue Geiler de Kaysersberg 67411 Illkirch Cedex France SRN #: FR-A-000003900 T +33 3 88 40 67 40 https://www.rmoeurope.com/

1.4. Emergency telephone number

Emergency number : Chemtrec: 800-424-9300 (domestic); 1-703-527-3887 (international)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Skin Irritant 2 H315
Eye Irritant 2A H319
Skin Sensitizer 1 H317
Full text of H- and EUH-statements: See section 16

Adverse physicochemical, human health and environmental effects

No additional information available.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



GHS07

Signal word (CLP) :

Danger

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Contains	: N/A
Hazard statements (CLP)	: H315 – Causes skin irritation H319 – Causes serious eye irritation H317 – May cause an allergic skin reaction
Precautionary statements (CLP)	: P280 – Wear protective gloves/protective clothing/eye protection/face protection P305+P351+P338 – If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313 – If eye irritation persists: Get medical advice/attention P302+P352 – If on skin: Wash with plenty of soap and water P332+P313 – If skin irritation occurs: Get medical advice/attention P273 – Avoid release to the environment. P501 – Dispose of contents and container in accordance with local and national regulations

2.3. Other hazards

None known.

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
2-Propenoic acid, 2-methyl-, (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] ester	CAS # 1565-94-2	45-70	Skin Irrit. 3, H316 Eye Irrit. 2B, H320
Poly(oxy-1,2-ethanediyl), alpha, alpha'-((1-methylethylidene)di-4,1-phenylene)bis(omega-((2-methyl-1-oxo-2-propen-1-yl)oxy)-	CAS # 41637-38-1	5-10	Skin Irrit. 2, H315 Eye Irrit. 2B, H320 Skin Sens. 1, H317 STOT (SE) Respiratory Tract 3, H335
2-Propenoic acid, 2-methyl-, (tetrahydro-2-furanyl)methyl ester	2455-24-5	15-35	Flammable Liquid 4, H227 Skin Sens. 1, H317 Eye Irrit. 2B, H320 STOT (SE) Respiratory Tract 3, H335 Repr. Tox. 2, H361
2-Hydroxyethyl methacrylate	868-77-9	5-10	Skin Sens. 1B, H317 Eye Irrit. 2B, H320
2-Propenoic acid, 2-methyl-, 1,1'-(2-ethyl-2-(((2-methyl-1-oxo-2-propen-1-yl)oxy)methyl)-1,3-propanediyl) ester	3290-92-4	1-5	Acute aquatic tox. 2, H401 Chronic aquatic tox. 2, H411
2-Propenoic acid, 2-methyl-, 2-(dimethylamino)ethyl ester	2867-47-2	1-5	Flammable Liquid 4, H227 Acute Tox., Oral 4, H302 Acute Tox., Dermal 4, H312 Skin Corrosion 1, H314 Serious Eye Damage 1, H318 Skin Sens. 1, H317 Repr. Tox. 2, H361 Acute aquatic tox. 3, H402

Full text of H- and EUH-statements: see section 16

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SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures after inhalation : No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of dusts or fumes, remove to fresh air and get medical attention if cough or other symptoms develop.
- First-aid measures after skin contact : Wash with soap and water.
- First-aid measures after eye contact : Immediately flush eyes with plenty of water for at least 15 minutes. Get immediate medical attention, if irritation persists.
- First-aid measures after ingestion : Do not induce vomiting, seek medical attention.

4.2. Most important symptoms and effects, both acute and delayed

- Symptoms/effects after skin contact : Not expected to present a significant hazard under anticipated conditions of normal use.
- Symptoms/effects after eye contact : Not expected to present a significant hazard under anticipated conditions of normal use. May cause eye irritation.

4.3. Indication of any immediate medical attention and special treatment needed

Not applicable.

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : See Section 5.3.

5.2. Special hazards arising from the substance or mixture

- Hazardous decomposition products in case of fire : Not determined.

5.3. Advice for firefighters

- Protection during firefighting : Firefighters should wear full emergency equipment and approved positive pressure self-containing breathing apparatus.



SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

- Emergency procedures : Remove all ignition sources such as open flames, spark producing equipment, pilot lights, etc. Avoid contact with skin, eyes or clothing. Wear appropriate protective clothing as described in Section 8.

6.1.2. For emergency responders

- Protective equipment : Recommended personal protective equipment for containment and clean-up



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6.2. Environmental precautions

Prevent entry into sewers and waterways. Report releases as required by local, state, and national authorities. Avoid contact with skin, eyes or clothing. Wear appropriate protective clothing as described in Section 8.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Wipe up with cloth, soap and water.
Other information : N/A

6.4. Reference to other sections

Refer to Section 8 and Section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Avoid contact with the eyes, skin and clothing. Wear protective clothing and equipment as described in Section 8. Use only with adequate ventilation. Wash thoroughly after handling.
Hygiene measures : N/A

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : See product labeling. Keep container closed to prevent contamination.

7.3. Specific end use(s)

Orthodontic bonding adhesive.

SECTION 8 : Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

None required under normal product handling conditions.

8.2.2. Personal protection equipment

Personal protective equipment symbol(s):



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8.2.2.1. Eye and face protection

Eye protection:

Wear eye protection.

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing and gloves.

Hand protection:

Wear suitable protective clothing and gloves.

8.2.2.3. Respiratory protection

Respiratory protection:

None should be needed under normal use.

8.2.2.4. Thermal hazards

None required.

8.2.3. Environmental exposure controls

Environmental exposure controls:

No additional information available.

Other information:

No additional information available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Homogeneous viscous liquid
Colour	: Pale yellow
Appearance	: No data
Odour	: Fruity ester-like
Odour threshold	: No data
Melting point	: No data
Freezing point	: No data
Boiling point	: No data
Flammability	: No data
Lower explosion limit	: No data
Upper explosion limit	: No data
Flash point	: No data
Auto-ignition temperature	: No data
Decomposition temperature	: No data
pH	: No data
pH solution	: No data
Viscosity, kinematic	: No data
Solubility	: Insoluble in water
Partition coefficient n-octanol/water (Log Kow)	: No data
Vapour pressure	: No data
Vapour pressure at 50°C	: No data
Density	: No data
Relative density	: 1.10-1.12 g/cc @ 25°C/77°F
Relative vapour density at 20°C	: No data
Particle size	: No data

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

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SECTION 10: Stability and reactivity

10.1. Reactivity

Stable at ambient temperature and under normal conditions of use.

10.2. Chemical stability

Stable at standard temperature and pressure.

10.3. Possibility of hazardous reactions

None.

10.4. Conditions to avoid

Keep away from heat, sparks, flames, and other sources of ignition.

10.5. Incompatible materials

High temperatures, visible light sources, strong oxidizing agents. Keep away from sunlight and open flames.

10.6. Hazardous decomposition products

Oxides of carbon when burned.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral) : No data
Acute toxicity (dermal) : No data
Acute toxicity (inhalation) : No data

2-Propenoic acid, 2-methyl-,(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] ester (CAS # 1565-94-2)

LD50 oral	Not available.
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Poly(oxy-1,2-ethanediyl), alpha,alpha'-((1-methylethylidene)di-4,1-phenylene)bis(omega-((2-methyl-1-oxo-2-propen-1-yl)oxy)- (CAS # 41637-38-1)

LD50 oral rat	>2000 mg/kg
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2-Propenoic acid, 2-methyl-, (tetrahydro-2-furanyl)methyl ester (CAS # 2455-24-5)

LD50 oral (estimate)	4003 mg/kg
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2-Hydroxyethyl methacrylate (CAS # 868-77-9)

LD50 oral rat	>5000 mg/kg
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2-Propenoic acid, 2-methyl-, 1,1'-(2-ethyl-2-(((2-methyl-1-oxo-2-propen-1-yl)oxy)methyl)-1,3-propanediyl) ester (CAS # 3290-92-4)

LD50 oral rat	>2000 mg/kg
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2-Propenoic acid, 2-methyl-, 2-(dimethylamino)ethyl ester (CAS # 2867-47-2)

LD50 oral rat	1751 mg/kg
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11.2. Information on other hazards

No additional information available.

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SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : No data
Hazardous to the aquatic environment, short-term (acute) : No data
Hazardous to the aquatic environment, long-term (chronic) : No data

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

No data available.

12.6. Endocrine disrupting properties

No data available.

12.7. Other adverse effects

No data available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose in accordance with all national and local regulations.
Ecology - waste materials : None currently known.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

14.1. UN number or ID number

Not applicable.

14.2. UN proper shipping name

Not dangerous goods.

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : Not applicable

IMDG

Transport hazard class(es) (IMDG) : Not applicable

IATA

Transport hazard class(es) (IATA) : Not applicable

AND

Transport hazard class(es) (ADN) : Not applicable

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RID

Transport hazard class(es) (RID) : Not applicable

14.4. Packing group

Not applicable

14.5. Environmental hazards

Dangerous for the environment : Not applicable

Marine pollutant : Not applicable

14.6. Special precautions for user

Overland transport

Not applicable

Transport by sea

Not applicable

Air transport

Not applicable

Inland waterway transport

Not applicable

Rail transport

Not applicable

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

All components requiring registration have been pre-registered.

REACH Annex XIV (Authorisation List)

All components requiring registration have been pre-registered.

REACH Candidate List (SVHC)

All components requiring registration have been pre-registered.

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals).

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants).

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer).

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors).

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances).

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15.1.2. National regulations

- *2-Propenoic acid, 2-methyl-, (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] ester* (CAS # 1565-94-2) is listed on the United States TSCA (Toxic Substances Control Act) inventory.
- *Poly(oxy-1,2-ethanediyl), alpha, alpha'-((1-methylethylidene)di-4,1-phenylene)bis(omega-((2-methyl-1-oxo-2-propen-1-yl)oxy)-* (CAS # 41637-38-1) is listed on the United States TSCA (Toxic Substances Control Act) inventory.
- *2-Propenoic acid, 2-methyl-, (tetrahydro-2-furanyl)methyl ester* (CAS # 2455-24-5) is listed on the United States TSCA (Toxic Substances Control Act) inventory.
- *2-Hydroxyethyl methacrylate* (CAS # 868-77-9) is listed on the United States TSCA (Toxic Substances Control Act) inventory.
- *2-Propenoic acid, 2-methyl-, 1,1'-(2-ethyl-2-(((2-methyl-1-oxo-2-propen-1-yl)oxy)methyl)-1,3-propanediyl) ester* (CAS # 3290-92-4) is listed on the United States TSCA (Toxic Substances Control Act) inventory.
- *2-Propenoic acid, 2-methyl-, 2-(dimethylamino)ethyl ester* (CAS # 2867-47-2) is listed on the United States TSCA (Toxic Substances Control Act) inventory.

15.2. Chemical safety assessment

None required.

SECTION 16: Other information

Indication of changes			
Section	Changed item	Change	Comments
N/A	N/A	N/A	N/A

Full text of H- and EUH-statements:	
Eye Irrit. 2A	Serious eye damage / eye irritation Category 2A
Skin Irrit. 2	Skin corrosion irritant Category 2
Skin Sens. 1	Sjvub sensitization Category 1
H227	Combustible liquid.
H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H316	Causes mild skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye damage.
H320	Causes eye irritation.
H335	May cause respiratory irritation.
H361	Suspected of damaging fertility or the unborn child.
H401	Toxic to aquatic life.
H402	Harmful to aquatic life.
H411	Toxic to aquatic life with long-lasting effects.

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.