



TruLock® Primer Activated Adhesive

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® Primer Activated Adhesive

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 adhesive

1.2.2. Uses advised against

Use of the substance/mixture : For professional use only

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_AR_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 (Outside of U.S.)

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 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]

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Hazard pictograms (CLP)



GHS07

Signal word (CLP)

: Danger

Contains

: No data

Hazard statements (CLP)

: H241 - Heating may cause a fire or explosion

H315 - Causes skin irritation

H317 - May cause an allergic skin reaction

H318 - Causes serious eye damage

H319 - Causes serious eye irritation

H335 - May cause respiratory irritation

Xi, Xn - Irritant and harmful

R22 - Harmful if swallowed

R36/37/38 - Irritating to eyes, respiratory systems and skin

Precautionary statements (CLP)

: P201 - Obtain special instructions before use

P202 - Do not handle until all safety precautions have been read and understood

P220 - Keep/Store away from clothing/ combustible materials.

P261 - Avoid breathing dust/fume/gas/mist/vapors/spray

P264 - Wash ... thoroughly after handling

P264+P265 - Wash hands thoroughly after handling. Do not touch eyes.

P271 - Use only outdoors or in a well-ventilated area.

P272 - Contaminated work clothing should not be allowed out of the workplace

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P302+P352 - IF ON SKIN: Wash with plenty of soap and water

P304+P340

P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

P308+P313 - IF exposed or concerned: Get medical advice/attention

P310 - Immediately call a POISON CENTER/doctor

P319 - Get medical help if you feel unwell.

P321 - Specific treatment (see ... on this label)

P332+P313 - If skin irritation occurs: Get medical advice/attention

P333+P313 - If skin irritation or rash occurs: Get medical advice/attention

P337+P313 - If eye irritation persists: Get medical advice/attention

P362 - Take off contaminated clothing

P362+P364 - Take off contaminated clothing and wash it before reuse

P403+P233 - Store in a well-ventilated place. Keep container tightly closed.

P405 - Store locked up

P501 - Dispose of contents and container in accordance with local and national regulations.

S15 - Keep away from heat

S23 - Do not breathe vapor

S24/25 - Avoid contact with skin and eyes

S26/28 - Wash with plenty of water

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 %.

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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]
Bis GMA	CAS # 1565-94-2	15-25	H318 – Eye Dam. 1 H317 – Skin Sens. 1
Silica	CAS # 7631-86-9	65-80	Not classified
Alkyl dimethacrylate	CAS # 109-16-0	0-10	H315 – Skin Irrit. 2 H317 – Skin Sens. 1 H319 – Eye Irrit. 2 H335 – STOT SE 3
Peroxide Initiator	CAS # 94-36-0	<5	H317 – Skin Sens. 1 H319 – Eye Irrit. 2

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

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: No data
First-aid measure after inhalation	: No data
First-aid measures after skin contact	: Wash off with soap and water. If irritation persists, consult a physician.
First-aid measures after eye contact	: Flush with plenty of water. Seek medical attention by an Ophthalmologist.
First-aid measures after ingestion	: Do not induce vomiting, seek medical attention.

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

Symptoms/injuries	: Not expected to present a significant hazard under anticipated conditions of normal use.
Symptoms/injuries after inhalation	: No data
Symptoms/effects after skin contact	: May cause skin sensitization.
Symptoms/effects after eye contact	: May cause eye and skin irritation.
Symptoms/injuries after ingestion	: May be harmful if swallowed.

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

Immediate medical attention should not be required except in cases of high quantities of ingestion or inhalation.

Note to Physicians (Treatment, Testing, and Monitoring): Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Use Chemical Foam, Carbon Dioxide, or Dry Chemical.
Unsuitable extinguishing media	: Unknown

5.2. Special hazards arising from the substance or mixture

Fire hazard	: Heat can initiate exothermic polymerization.
Explosion hazard	: Heat can initiate exothermic polymerization.
Reactivity	: No data

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5.3. Advice for firefighters

Protection during firefighting

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



Firefighting instructions

: Cool fire exposed containers with water spray.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures / Protective equipment

: 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

Emergency procedures

: No data

Protective equipment

: No data

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. Avoid breathing vapors. Wear appropriate protective clothing as described in Section 8.

6.3. Methods and material for containment and cleaning up

For containment

: No data

Methods for cleaning up

: Clean up with absorbent material and remove residue with alcohol damp wipe. Rinse spill area with water. Use nonsparking tools and equipment.

6.4. Reference to other sections

See Section 8.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling

: Avoid unnecessary exposure.

Hygiene measures

: No data.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions

: Store in a cool, dry, well-ventilated area away from heat, direct sunlight and all sources of ignition. Store away from incompatible materials. Keep container closed to prevent contamination.

Incompatible products

: No data

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7.3. Specific end use(s)

No specific end use.

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):



8.2.2.1. Eye and face protection

Eye protection:

Chemical safety goggles should be worn if needed to avoid eye contact.

8.2.2.2. Skin protection

Hand protection:

Wear impervious gloves such as natural rubber or neoprene if needed to avoid skin contact. Consult glove supplier for thickness and breakthrough times.

8.2.2.3. Respiratory protection

Respiratory protection:

None should be needed under normal use. If exposure limits are exceeded an approved respirator or supplied air respirator appropriate should be used. Respirator selection and use should be based on contaminant type, form and concentration. Follow applicable regulations and good Industrial Hygiene practice.

8.2.2.4. Thermal hazards

None required.

8.2.3. Environmental exposure controls

Environmental exposure controls:

No additional information available.

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Paste
Colour	: No data
Appearance	: Paste
Odour	: No data
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	: No data
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	: No data
Relative vapour density at 20°C	: No data
Particle size	: No data
Specific gravity	: 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

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable in normal storage.

10.2. Chemical stability

Stable at standard temperature and pressure.

10.3. Possibility of hazardous reactions

No data

10.4. Conditions to avoid

Temperatures over 40°C and contamination.

10.5. Incompatible materials

Amines and reducing agents

10.6. Hazardous decomposition products

Carbon oxides.

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SECTION 11: Toxicological information

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

Acute toxicity (oral) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

Silica, amorphous, fumed, crystalline-free (CAS # 112945-52-5)	
LD50 - Oral - Rat	5000 mg/kg
ATE (Oral)	5000 mg/kg

Skin corrosion/irritation : Causes skin irritation
Serious eye damage/irritation : Causes serious eye irritation
Respiratory or skin sensitisation : May cause an allergic skin reaction
Germ cell mutagenicity : Not classified
Carcinogenicity : Not classified
Respiratory or skin sensitisation : Not classified
Germ cell mutagenicity : Not classified
Carcinogenicity : Not classified
Reproductive toxicity : Not classified
STOT-single exposure : Not classified

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

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

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

Waste disposal product : None currently known.

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Sewage disposal recommendations : Dispose in accordance with all national and local regulations.
Ecology - waste materials : Dispose in accordance with all national and local regulations.

SECTION 14: Transport information

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

14.1. UN number or ID number

N/A

14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not Dangerous Goods
Proper Shipping Name (IMDG) : Not Dangerous Goods
Proper Shipping Name (IATA) : Not Dangerous Goods
Proper Shipping Name (ADN) : Not Dangerous Goods
Proper Shipping Name (RID) : Not Dangerous Goods

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : N/A

IMDG

Transport hazard class(es) (IMDG) : N/A

IATA

Transport hazard class(es) (IATA) : N/A

AND

Transport hazard class(es) (ADN) : N/A

RID

Transport hazard class(es) (RID) : N/A

14.4. Packing group

Packing group (ADR) : N/A
Packing group (IMDG) : N/A
Packing group (IATA) : N/A
Packing group (ADN) : N/A
Packing group (RID) : N/A

14.5. Environmental hazards

Dangerous for the environment : N/A
Marine pollutant : N/A
Other information : N/A

14.6. Special precautions for user

Overland transport

Not Dangerous Goods

Transport by sea

Not Dangerous Goods

Air transport

Not Dangerous Goods

Inland waterway transport

Not Dangerous Goods

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Rail transport

Not Dangerous Goods

14.7. Maritime transport in bulk according to IMO instruments

Not Dangerous Goods

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)

15.1.2. National regulations

This product is not 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:	
H315	May cause skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

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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.