



TruLock® Light Activated Bracket 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 Light Activated Bracket Adhesive
Other means of identification : Light Cure Adhesive Paste

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 dental 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 (international)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Skin irritation, Category 2 H315
Eye irritation, Category 2 H319

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)

: Warning

Contains

: N/A

Hazard statements (CLP)

: H315 - Causes skin irritation

H319 - Causes serious eye irritation

Precautionary statements (CLP)

: P264 - Wash hands thoroughly after handling

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

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

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

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

P321 - Specific treatment (see Section 4)

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

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

P362 - Take off contaminated clothing

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-, 1,6-hexanediyl ester	CAS # 6606-59-3	5-10	Skin Irrit. 2, H315 Eye Irrit. 2B, H320 Spec Target Organ Tox. H335
2-Propenoic acid, 2-methyl-, (1-methylethylidene)bis(4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)) ester	CAS # 1565-94-2	10-15	Skin Irrit. 3, H316 Eye Irrit. 2B, H320

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

: Remove victim to fresh air. If breathing is difficult have qualified personnel administer oxygen. If breathing has stopped, administer artificial respiration and get immediate medical attention.

First-aid measures after skin contact

: Remove contaminated clothing. Wash skin thoroughly with soap and water. If irritation develops, get medical attention. Launder clothing before re-use.

First-aid measures after eye contact

: Immediately flush victim's eyes with large quantities of water for several minutes, holding the eyelids apart. Get medical attention if irritation persists.

First-aid measures after ingestion

: Rinse out mouth with water. Do not induce vomiting. Never give anything by mouth to an unconscious or drowsy person. Get immediate medical attention.

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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 irritation. May cause skin sensitisation.
Symptoms/effects after eye contact	: May cause eye irritation.
Symptoms/injuries after ingestion	: May be harmful if swallowed.

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

If medical advice is needed, have product container or label at hand.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Use chemical foam, CO ₂ , dry chemical powder, water spray. Note: Water may be ineffective in extinguishing the fire.
Unsuitable extinguishing media	: No data

5.2. Special hazards arising from the substance or mixture

Fire hazard	: Material may burn if exposed to flame.
Explosion hazard	: No data
Reactivity	: No data

5.3. Advice for firefighters

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

Protection during firefighting :



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

Protective equipment :



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

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Protective equipment



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 containment / cleaning up : Clean up with absorbent material and remove residue with alcohol damp wipe. Rinse spill area with water. Use non-sparking tools and equipment.

6.4. Reference to other sections

See Section 8 and Section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

General : Avoid contact with the eyes, skin and clothing. Avoid breathing vapors. Wear protective clothing and equipment as described in Section 8. Use only with adequate ventilation. Wash thoroughly after handling. Keep away from heat, sparks, flames, and other sources of ignition.

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

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

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8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure adequate ventilation, especially in confined areas. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure.

8.2.2. Personal protection equipment

Personal protective equipment symbol(s):

Safety glasses. Gloves.



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 containment 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.

Other information:

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: No data
Appearance	: Paste
Odour	: Characteristic
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

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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	: 1.85 g/cc @ 25°C / 77°F
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 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

May occur in large quantities.

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

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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

Chemical Name and CAS Number

LC50	No data
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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.
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

No additional information required.

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

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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) : Not regulated

Packing group (IMDG) : Not regulated

Packing group (IATA) : Not regulated

Packing group (ADN) : Not regulated

Packing group (RID) : Not regulated

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

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)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

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REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

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

U.S. Federal Regulations

2-Propenoic acid, 2-methyl-, (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] ester (1565- 2) is listed on the United States TSCA (Toxic Substances Control Act) inventory

International Regulations

Canadian Workplace Hazardous Materials Information System (WHMIS): Medical devices are not subject to WHMIS.

Canadian Environmental Protection Act: This product is a medical device and not subject to chemical notification requirements.

This SDS has been prepared according to the criteria of the Controlled Products Regulation (CPR) and the SDS contains all of the information required by the CPR.

European Inventory of Existing Chemicals (EINECS): This product is a medical device and not subject to chemical notification requirements.

EU REACH: All components requiring registration have been pre-registered.

Australian Inventory of Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

China Inventory of Existing Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Japanese Existing and New Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Korean Existing Chemicals List: This product is a medical device and not subject to chemical notification requirements.

Philippine Inventory of Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

15.2. Chemical safety assessment

None required.

SECTION 16: Other information

Indication of changes			
Section	Changed item	Change	Comments
All sections	Supersedes: SDS-028 Rev006, October 9, 2020	Date updated: 11/23/2020 Change Control Document #: DCN 5626, 7155, 7727, 7808 Revision Summary: 10/7/17 Converted MSDS to Reach SDS. Updated all sections. 1/28/20 Updated all sections. 10/9/20 Removed the sodium fluoride, no longer in the formula. 11/23/20 Added PN 303-0600.	Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau, ESIS, Country websites for occupational exposure limits.

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Full text of H- and EUH-statements:

H315	Skin corrosion/irritation Category 2
H316	Skin corrosion/irritation Category 3
H319	Serious eye damage/eye irritation Category 2A
H320	Serious eye damage/eye irritation Category 2B
H335	Specific target organ toxicity, single exposure; Respiratory tract irritation Category 3

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.