

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 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	FDA Registration: According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations
SRN #: US-MF-00003482 T 1 800 525 6735 customerservice@rmortho.com https://rmortho.com/	FDA Registration: 1718476
Australian Sponsor:	EC Representative:
AB Orthodontics PTY LTD	RMO Europe
13/15 Collins St	300 rue Geiler de Kaysersberg
Melbourne VIC 3000	67411 Illkirch Cedex France
Australia	SRN #: FR_AR_000003900
T <u>+61 3 9650 2526</u>	T +33 3 88 40 67 40
	https://www.rmoeurope.com/

1.4. Emergency telephone number

Emergency number : <u>Chemtrec</u>

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]

No additional information available

Adverse physicochemical, human health and environmental effects

No additional information available.

Safety Data Sheet

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

2.2. Label elements

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

Hazard pictograms (CLP)



GHS07

Signal word (CLP) : No data
Contains : No data

Hazard statements (CLP) : H241 - Heating may cause a fire or explosion

H315 - Causes skin irritation H316 - Causes mild skin irritation H317 - May cause an allergic skin reaction

H319 - Causes serious eye irritation
H335 - May cause respiratory irritation

Precautionary statements (CLP) : P201 - Obtain special instructions before use

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

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

P264 - Wash ... thoroughly after handling

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

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

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

P405 - Store locked up

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]
Triethylene Glycol Dimethacrylate	109-16-0	5-10	Skin Sensitization (Cat 1), H317
2-Propenoic acid, 2-methyl-,(1-methylethylidene)bis{4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] ester	1565-94-2	30-65	Skin Irritation (Cat. 3), H316 Eye Irritation (Cat. 2A), H319
iso-Butyl Methacrylate	97-86-9	10-30	Skin Irritation (Cat. 3), H316 Eye Irritation (Cat. 2A), H319

Safety Data Sheet

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

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Benzoyl Peroxide	94-36-0	1-5	Organic Peroxides (Type B), H241 Eye Irritation (Cat. 2A), H319 Skin Sensitization (Cat 1), H317
N,N-Bis(2-Hydroxyethyl)-p- Toluidine	3077-12-1	1-5	Skin Irritation (Cat. 3), H316 Eye Irritation (Cat. 2A), H319
Silica	7631-86-9	60-90	H335

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 : Remo ve 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.

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.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Use Chemical Foam, CO2, 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

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







Safety Data Sheet

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

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 heading 8, Exposure Controls and Personal Protection

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : 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.

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

7.3. Specific end use(s)

No specific end use.

Safety Data Sheet

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

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.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Solid (Paste) / Liquid (Primer)

Safety Data Sheet

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

Colour : No data

Appearance : Solid (Paste) / Clear Liquid (Primer)

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 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 : 1.93g/cc; 1.03/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.

Safety Data Sheet

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

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.

Sewage disposal recommendations : Dispose in accordance with all national and local regulations.

Safety Data Sheet

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

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

Safety Data Sheet

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

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:	
Eye Irrit. 2A	Serious eye damage/ eye irritation Category 2A
Skin Irrit. 2	Skin corrosion irritant Category 2
Skin Sens. 1	Skin sensitization Category 1
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.

Safety Data Sheet

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

Full text of H- and EUH-statements:	
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

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.