



SAFETY DATA SHEET

Safety Data Sheet (in compliance with Regulation (EC) 1907/2006,
Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

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Current Revision: IN

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SECTION 1 - IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

Product Identifier:

Trade Name (as labeled):	TRULOCK® Primer Activated Adhesive and Primer
Product Form:	Mixture
Part / Item Number:	J04010, J04011, J04012, J04013

Relevant identified Uses of the Substance or Mixture and Uses Advised Against:

Recommended Use:	Orthodontic Adhesive
Restrictions on Use:	For Professional Use Only

Details of the Supplier of the Safety Data Sheet:

Manufacturer / Supplier Name:	RMO, INC.
Manufacturer / Supplier Address:	650 WEST COLFAX AVENUE DENVER, CO 80204 U.S.A
Manufacturer / Supplier Telephone Number:	(303) 592-8200 / (800) 525-6375

Emergency Telephone Number:

Emergency Contact Telephone Number:	Chemtrec (800) 424-9300 / (703) 527-3887
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SECTION 2 - HAZARDS IDENTIFICATION

Classification of the Substance or Mixture:

This Product as manufactured is a solid composed encapsulated chemical ingredients. No hazardous exposures are anticipated during normal product handling and use conditions.

GHS Classification:		
Health	Environmental	Physical
Skin Irritant 2 (H315)	Not Hazardous	No Physical Hazards
Eye Irritant 2A (H319)		
Skin Sensitizer (H317)		

EU Classification: Irritant (Xi), R22, R36/37/38, R43

Label Elements:

Hazard pictograms (GHS-US)



Harmful (GHS07)

Signal Word: Danger



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Hazard Phrases	Precautionary Phrases
H241 – Heating May cause a fire or explosion H315 – Causes skin irritation H316 – Causes mild skin irritation H317 – May cause allergic skin reaction H319 – Causes serious eye irritation H335 – May cause respiratory irritation	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 – Special 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

Other Hazards:

None known.

Unknown Acute toxicity (GHS-US):

No data available

SECTION 3 - COMPOSITION / INFORMATION ON INGREDIENTS

Substances:

Not Applicable

Mixture:

Hazardous Components	C.A.S. #	GHS-US Classification	WT %*
Triethylene Glycol Dimethacrylate	109-16-0	Skin Sensitization (Cat 1), H317	5-10
2-Propenoic acid, 2-methyl-,(1-methylethylidene)bis{2-hydroxy-3,1-propanediyl} ester	1565-94-2	Skin Irritation (Cat. 3), H316 Eye Irritation (Cat. 2A), H319	30-65
<i>iso</i> -Butyl Methacrylate	97-86-9	Skin Irritation (Cat. 3), H316 Eye Irritation (Cat. 2A), H319	10-30

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Hazardous Components	C.A.S. #	GHS-US Classification	WT %*
Benzoyl Peroxide	94-36-0	Organic Peroxides (Type B), H241 Eye Irritation (Cat. 2A), H319 Skin Sensitization (Cat 1), H317	1-5
N,N-Bis (2-Hydroxyethyl)-p-Toluidine	3077-12-1	Skin Irritation (Cat. 3), H316 Eye Irritation (Cat. 2A), H319	1-5
Silica	7631-86-9	H335	60-90

* Specific identity and/or exact percentage have been withheld for trade secret
Refer to Section 16 for the full text of the GHS and EU Classifications.

SECTION 4 - FIRST AID MEASURES

Description of First Aid Measures:

Eye	Immediately flush victim's eyes with large quantities of water for several minutes, holding the eyelids apart. Get medical attention if irritation persists.
Skin	Remove contaminated clothing. Wash skin thoroughly with soap and water. If irritation develops, get medical attention. Launder clothing before re-use.
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.
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.

Most Important Symptoms and Effects, Both Acute and Delayed:

Not expected to present a significant hazard under anticipated conditions of normal use. May cause eye and skin irritation. May cause skin sensitization. May be harmful if swallowed.

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 - FIRE-FIGHTING MEASURES

Extinguishing Media:

Use Chemical Foam, CO₂, Dry Chemical Powder, Water Spray.

NOTE: water may be ineffective in extinguishing the fire.





Special Hazards Arising from the Substance or Mixture:

Material may burn if exposed to flame

Advice for Fire-Fighters:

Fire Fighting Procedures:	Cool fire exposed containers with water spray
Precautions for Fire Fighters:	Firefighter should wear full emergency equipment and approved positive pressure self-containing breathing apparatus.

Recommended Protective Equipment for Fire Fighters:



Eyes / Face	Hands	Respiratory	Thermal
 Face Shield	 Hand Protection	 Air Purifying Respirator	 Chemical Protective Clothing

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SECTION 6 - ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and 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.

Recommended Protective Equipment for Containment and Clean-up:			
Eyes / Face	Hands	Respiratory	Thermal
 Goggles	 Hand Protection		

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.

Methods and Material for Containment and 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.

Reference to Other Sections:

Refer to Section 8 for Personal Protective Equipment and Section 13 for Disposal information.

SECTION 7 - HANDLING AND STORAGE

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.

Conditions for Safe Storage, Including Any Incompatibilities:

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.

Specific End Use(s):

No specific end use.

SECTION 8 - EXPOSURE CONTROLS / PERSONAL PROTECTIONS



Control Parameters:

No additional information available.

Exposure Controls:

Appropriate Engineering Controls: None required under normal product handling conditions.

Individual Protection Measures (PPE):

Recommended Protective Equipment for Containment and Clean-up:			
Eyes / Face	Hands	Respiratory	Thermal
 Goggles	 Hand Protection		
Specific Eye/face Protection:		Chemical safety goggles should be worn if needed to avoid eye contact.	



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Recommended Protective Equipment for Containment and Clean-up:	
Specific Skin Protection:	Wear impervious gloves such as natural rubber or neoprene if needed to avoid skin contact. Consult glove supplier for thickness and breakthrough times.
Specific Respiratory Protection:	None should be needed under normal use. If exposure limits are exceeded, and 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.
Specific Thermal Hazards:	None required.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Information on Basic Physical and Chemical Properties:

Physical state:	Solid (Paste) / Liquid (Primer)	Relative density:	1.93g/cc;1.03/cc @ 25°C / 77°F
Appearance:	Solid (Paste) / Clear Liquid (Primer)	Explosive limits	Not determined
Odor:	Characteristic	Vapor pressure (mmHg):	Not determined
Odor threshold:	Not determined	Vapor density:	Not determined
pH:	Not determined	Solubility(ies):	Insoluble in water
Melting / Freezing point:	Not determined	Partition coefficient: n-octanol/water:	Not determined
Initial boiling point and boiling range:	Not determined	Auto-ignition temperature:	Not determined
Flash point:	Not determined	Decomposition temperature:	Not determined
Evaporation rate:	Not determined	Viscosity:	Not determined
Flammability (solid, gas):	Not determined	Oxidizing Properties:	Not determined
Explosive properties:	Not determined		

Other Information:

None available

SECTION 10 - STABILITY AND REACTIVITY

Reactivity:

Stable at ambient temperature and under normal conditions of use.

Chemical Stability:

Stable at standard temperature and pressure.

Possibility of Hazardous Reactions:

May occur in large quantities.

Conditions to Avoid:

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

Incompatibility materials:



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

Hazardous Decomposition Products:

Oxides of carbon when burned.

SECTION 11 - TOXICOLOGICAL INFORMATION**Information on Toxicological Effects:**

Silica, amorphous, fumed, crystalline-free (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 sensitization	May cause an allergic skin reaction
Germ cell mutagenicity	Not classified
Carcinogenicity	Not classified

SECTION 12 - ECOLOGICAL INFORMATION**Toxicity:**

No data available

Persistence and Degradability:

No data available

Bio-accumulative Potential:

No data available

Mobility in Soil:

No data available

Results of PBT and vPvB Assessment:

No data available

Other Adverse Effects:

No data available

SECTION 13 - DISPOSAL CONSIDERATIONS**Waste Treatment Methods:**

Regulations	Dispose in accordance with all national and local regulations.
Properties (Physical / Chemical) Affecting Disposal:	None currently known.
Waste Treatment Recommendations:	Dispose in accordance with national and local regulations.

SECTION 14 - TRANSPORT INFORMATION**UN number:**

Not applicable

UN proper shipping name:

Not Dangerous Good

Transport hazard class(es):

Not applicable

Packing group:

Not applicable



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Environmental hazards:

Not applicable

Special precautions for user:

- ADR-road: Not Dangerous Goods
- RID-rail: Not Dangerous Goods
- IMDG-sea: Not Dangerous Goods
- IATA-air: Not Dangerous Goods

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:

Not applicable

SECTION 15 - REGULATORY INFORMATION

Safety, Health and Environmental Regulations / Legislation Specific for the Substance or Mixture:

U.S. Federal Regulations

This product is not 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
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

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

Chemical Safety Assessment

None required.



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SECTION 16 - OTHER INFORMATION

HMIS Hazard Rating:

Health: 1	Flammability: 0	Reactivity: 0
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Full text of Classification abbreviations used in Section 2 and 3:

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.
H319	Causes serious eye irritation
H335	May cause respiratory irritation

Disclaimer: FOR ORTHODONTIC USE ONLY. The information and recommendations are taken from sources (raw material MSDS(s), SDS(s) and manufacturers knowledge) believed to be accurate; however, the manufacturer makes not warranty with respect to the accuracy of the information or suitability of the recommendation in the specific context of the intended use and determine whether they are appropriate.