

## SAFETY DATA SHEET: Pre-Applied Adhesive

**Section I – IDENTIFICATION**

<b>Product Name:</b>	Clear Read-Base® Pre-Applied Adhesive, Read-Base® RBX Pre-Applied Adhesive
<b>Common Name:</b>	Orthodontic Adhesive
<b>Material:</b>	Pre-Applied Adhesive
<b>Recommended Use:</b>	TP Orthodontics' products are intended for use in orthodontic treatment.
<b>Restrictions on Use:</b>	TP Orthodontics' products are intended for use by trained dental professionals and orthodontists, who have the primary responsibility to identify any possible contraindications that may preclude the use of this product. U.S. Federal law restricts this device to sale by or on the order of a dental professional.
<b>Product Manufacturer:</b>	TP Orthodontics, Inc. 100 Center Plaza La Porte, IN 46350-9672 USA Phone: 800-348-8856 Hours: M-Th 7a-4:30p Fax: 219-324-3029 Internet: <a href="http://www.tportho.com">www.tportho.com</a>
<b>Emergency Number:</b>	800-348-8856 Available during normal business hours: Monday-Thursday 7am to 5pm CST and Friday 7am to 12pm CST

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**Section II – HAZARD IDENTIFICATION**

**General Hazard Statement:** This SDS has been prepared in accordance with the U.S. OSHA Hazard Communication Standard, which requires the inclusion of known hazards of the product or ingredients regardless of the potential risk. The risks of the hazards communicated in this document may vary depending on the potential and type of exposure.

**Pictograms:****Signal word:**

Warning

**Classification of the substance or mixture:****GHS Classification in accordance with 29 CFR 1910.1200 (OSHA HCS)**

Skin irritation (Category 2)	H315
Eye irritation (Category 2A)	H319
Skin sensitization (Category 1)	H317

**Hazard statements:**

H315 -- Causes skin irritation  
H317 -- May cause an allergic skin reaction  
H319 -- Causes serious eye irritation

**Precautionary statements:**

P264 -- Wash hands 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  
P363 -- Wash contaminated clothing before reuse  
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  
P333+P313 -- If skin irritation or rash occurs, get medical advice/attention  
P337+P313 -- If eye irritation persists, get medical advice/attention  
P501 -- Dispose in a safe manner in accordance with local/national regulations.

**Hazards not otherwise classified (HNOC) or not covered by GHS:** None

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**Section III – COMPOSITION/ INFORMATION ON INGREDIENTS****Mixtures: \***

Clear Read-Base® Pre-Applied Adhesive

<b>Ingredient(s)</b>	<b>CAS No.</b>	<b>EC No.</b>	<b>Wt. %</b>
Bis-GMA	1565-94-2	216-367-7	8-11
Ethoxylated bis phenol A dimethacrylate	41637-38-1	N/A	<23
Butylated hydroxytoluene	128-37-0	204-881-4	<0.03

Readi-Base® RBX Pre-Applied Adhesive

<b>Ingredient(s)</b>	<b>CAS No.</b>	<b>EC No.</b>	<b>Wt. %</b>
Bis-GMA	1565-94-2	216-367-7	8-11
Ethoxylated bis phenol A dimethacrylate	41637-38-1	N/A	<23
Butylated hydroxytoluene	128-37-0	204-881-4	<0.03
Sodium fluoride	7681-49-4	231-667-8	<0.6

*\*No minor components need to be disclosed according to the applicable regulations.***Section IV – FIRST-AID MEASURES**

- Skin:** Take off contaminated clothing and immediately wash skin with soap and water. If signs/symptoms develop, get medical attention. Wash clothing before reuse.
- Eyes:** Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Remove contact lenses if easy to do and continue rinsing.
- Ingestion:** Do not induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.
- Inhalation:** Move into fresh air. If breathing difficulty occurs, get prompt medical attention.

**Section V – FIRE-FIGHTING MEASURES****Flash Point and Method:** NA**Flammability Limits:** NA**Auto-ignition Temperature:** NA

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**Melting Point:** NA

**General Hazard:** Not combustible in the shipped form

**Firefighting Instructions:** No special instructions for product shipped

**Firefighting Equipment:** No special equipment for product as shipped

**Combustion Products:** No hazardous decomposition products are expected

### Section VI – ACCIDENTAL RELEASE MEASURES

**General:** Avoid release to the environment. Prevent soil and water pollution. Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters. Wear respiratory protection. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. For personal protection, see section 8.

### Section VII - HANDLING AND STORAGE

**Storage Temperature:** Store at room temperature.

**Storage Pressure:** Not applicable.

**General Storage:** Keep product in a dry and well-ventilated place. Incompatible with strong bases and acids. Store out of direct sunlight

### Section VIII – EXPOSURE CONTROLS/ PERSONAL PROTECTION

#### Control Parameters

Product does not contain relevant quantities of components with critical values that have to be monitored at the workplace.

#### Personal Protection Equipment

**Eyes:** Safety glasses recommended. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

**Skin:** Gloves recommended when handling.

### Section IX – PHYSICAL AND CHEMICAL PROPERTIES

Clear Redit-Base® Pre-Applied Adhesive

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<b>Appearance</b>	Semi-clear paste
<b>Odor</b>	Slight acrylate odor
<b>Physical State</b>	Semi-solid paste
<b>pH</b>	N/A
<b>Melting/Boiling Point</b>	N/A
<b>Flash Point</b>	N/A
<b>Evaporation Rate</b>	N/A
<b>Flammability</b>	N/A
<b>Vapor Pressure</b>	N/A
<b>Vapor Density</b>	N/A
<b>Relative Density</b>	N/A
<b>Solubility in water</b>	N/A
<b>Auto-ignition Temp</b>	N/A
<b>Decomposition Temp</b>	N/A
<b>Viscosity</b>	2-4.5 million cps

### Readi-Base® RBX Pre-Applied Adhesive

<b>Appearance</b>	Light gray paste
<b>Odor</b>	Slight acrylate odor
<b>Physical State</b>	Semi-solid paste
<b>pH</b>	N/A
<b>Melting/Boiling Point</b>	N/A
<b>Flash Point</b>	N/A
<b>Evaporation Rate</b>	N/A
<b>Flammability</b>	N/A
<b>Vapor Pressure</b>	N/A
<b>Vapor Density</b>	N/A
<b>Relative Density</b>	N/A
<b>Solubility in water</b>	N/A
<b>Auto-ignition Temp</b>	N/A
<b>Decomposition Temp</b>	N/A
<b>Viscosity</b>	1-6 million cps

## Section X – STABILITY AND REACTIVITY

<b>Stability:</b>	Stable under recommended storage conditions.
<b>Reactivity:</b>	No data available.
<b>Incompatible Material:</b>	Strong bases, strong oxidizing agents.
<b>Conditions to Avoid:</b>	Direct sunlight. May polymerize on exposure to light. Extreme high or low temperatures.

## Section XI – TOXICOLOGICAL INFORMATION

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### Acute toxicity

Clear Read-Base® Pre-Applied Adhesive

Individual components:

Ingredient	Toxicology Data
Bis-GMA	Not classified – no animal test data available, high viscosity
Ethoxylated bis phenol A dimethacrylate	No data available
Butylated hydroxytoluene	LD50 Oral (Rat): > 6,000 mg/kg; LD50 Dermal (Rat): > 2,000 mg/kg

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Ingredient	Toxicology Data
Bis-GMA	Not classified – no animal test data available, high viscosity
Ethoxylated bis phenol A dimethacrylate	No data available
Butylated hydroxytoluene	LD50 Oral (Rat): > 6,000 mg/kg; LD50 Dermal (Rat): > 2,000 mg/kg
Sodium fluoride	LD50 Oral (Rat): > 6,000 mg/kg; LD50 Dermal (Rat): > 2,000 mg/kg

## Section XII – ECOLOGICAL INFORMATION

### Toxicity

Clear Read-Base® Pre-Applied Adhesive

**Bis-GMA:** No data available, high viscosity.

**Ethoxylated Bis Phenol A Dimethacrylate:** No data available.

#### Butylated hydroxytoluene

Toxicity to fish ( <i>Oryzias latipes</i> ), LC50	5.3 mg/l (48 h)
Toxicity to water flea ( <i>Daphnia magna</i> ), static test EC50	0.48 mg/l (48 h)
Toxicity to bacteria (Protozoa), growth inhibition EC50	1.7 mg/l (24 h)

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**Bis-GMA:** No data available, high viscosity.

**Ethoxylated Bis Phenol A Dimethacrylate:** No data available.

#### Butylated hydroxytoluene

Toxicity to fish ( <i>Oryzias latipes</i> ), LC50	5.3 mg/l (48 h)
Toxicity to water flea ( <i>Daphnia magna</i> ), static test EC50	0.48 mg/l (48 h)
Toxicity to bacteria (Protozoa), growth inhibition EC50	1.7 mg/l (24 h)

#### Sodium fluoride

Toxicity to sheepshead minnow ( <i>Cyprinodon variegatus</i> ), mortality NOEC	500 mg/l (96 h)
Toxicity to rainbow trout ( <i>Oncorhynchus mykiss</i> ), LC50	200 mg/l (96 h)
Toxicity to water flea ( <i>Daphnia magna</i> ), EC50	98 mg/l (48 h)

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**Section XIII – DISPOSAL CONSIDERATIONS**

**General:** Safely dispose in accordance with local/national regulations. Adhesive may be cured prior to disposal by exposing to ambient light.

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**Section XIV – TRANSPORTATION INFORMATION**

Department of Transportation (DOT) Hazard Class: Not regulated

Hazard label (DOT): Not regulated

Packing group (DOT): Not regulated

**Section XV – REGULATORY INFORMATION**

TSCA (Toxic Substances Control Act):  
Not Applicable

CERCLA (Comprehensive Response & Liability Act):  
Not Applicable

SARA Title III (Superfund Amendments & Reauthorization Act):  
311/312 Hazardous Categories – No chemicals in this product are subject to the reporting requirements of SARA Title III, Section 302.  
313 Product Ingredients – This product does not contain any chemical components with known CAS numbers that exceed the threshold reporting levels established by SARA Title III, Section 313.

**Clear Read-Base® RBX Pre-Applied Adhesive only:****Massachusetts Right to Know Components**

	<b><u>CAS No.</u></b>	<b><u>Revision Date</u></b>
2,6-di-tert-Butyl-p-cresol	128-37-0	1993-04-24
Sodium fluoride	7681-49-4	2007-03-01

**Pennsylvania Right to Know Components**

	<b><u>CAS No.</u></b>	<b><u>Revision Date</u></b>
Bisphenol A, ethoxylated, dimethacrylate	41637-38-1	
2,6-di-tert-Butyl-p-cresol	128-37-0	1993-04-24

**New Jersey Right to Know Components**

	<b><u>CAS No.</u></b>	<b><u>Revision Date</u></b>
Bisphenol A, ethoxylated, dimethacrylate	41637-38-1	
2,6-di-tert-Butyl-p-cresol	128-37-0	1993-04-24

**Read-Base® RBX Pre-Applied Adhesive only:****Massachusetts Right to Know Components**

	<b><u>CAS No.</u></b>	<b><u>Revision Date</u></b>
2,6-di-tert-Butyl-p-cresol	128-37-0	1993-04-24
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California Safe Drinking Water Act (Prop 65) listing: This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

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### Section XVI – OTHER INFORMATION

**HMIS Rating:**

Health hazard:	<b>2</b>	Temporary or minor injury may occur.
Flammability:	<b>1</b>	Materials that must be preheated before ignition will occur.
Physical hazard:	<b>0</b>	Minimal hazard

**NFPA Rating:**

Health hazard:	<b>2</b>	Short exposure could cause serious temporary or residual injury even though prompt medical attention was given.
Fire hazard:	<b>1</b>	Materials that require preheating before ignition/combustion can occur.
Reactivity hazard:	<b>0</b>	Normally stable, even under fire exposure conditions, and are not reactive with water.

**Full text of H-Statements referred to under Section 2:**

Skin Sens. 1	Skin sensitization Category 1
Skin Irrit. 2	Skin corrosion/irritation Category 2
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Aquatic Acute 1	Acute aquatic toxicity Category 1
Aquatic Chronic 1	Chronic aquatic toxicity Category 1
STOT SE 3	Special target organ toxicity – single exposure Category 3, Respiratory
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H335	May cause respiratory irritation
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects

All the information is collected from Supplier certificate of analysis, manufacturing process, technical files and known history from 70 years of experience and is believed to be correct as of the date issued.

By supplying above information, TP Orthodontics, Inc. assumes no legal responsibility of any kind for the accuracy, completeness, or use of the data supplied as well as the product mentioned in the foreclosure