

SAFETY DATA SHEET: Bondable Adhesive

Section I – IDENTIFICATION

Product Name:	eXact® Clear Orthodontic Adhesive
Common Name:	Orthodontic Adhesive
Material:	Bondable Adhesive
Recommended Use:	TP Orthodontics' products are intended for use in orthodontic treatment.
Restrictions on Use:	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.
Product Manufacturer:	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: www.tportho.com
Emergency Number:	800-348-8856 Available during normal business hours: Monday-Thursday 7am to 5pm CST and Friday 7am to 12pm CST

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: *

Ingredient(s)	CAS No.	EC No.	Wt. %**
Bis-GMA	1565-94-2	216-367-7	10-30
Urethane dimethacrylate	72869-86-4	276-957-5	<10
Triethylene glycol dimethacrylate	109-16-0	276-957-5	<5
Butylated hydroxytoluene	128-37-0	204-881-4	<1

No minor components need to be disclosed according to the applicable regulations.**The exact weight percentages of this composition have been withheld as a trade secret. Other ingredients in the composition are deemed non-hazardous in the final mixture.***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
- 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

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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.

Section VII - HANDLING AND STORAGE

Precautions for Safe Handling: Avoid prolonged and repeated contact with skin. Wash hands with soap and water after handling.

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 and away from sources of ignition.

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.

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Section IX – PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Translucent yellow paste
Odor	Slight acrylate odor
Physical State	Semi-solid paste
pH	N/A
Melting/Boiling Point	N/A
Flash Point	N/A
Evaporation Rate	N/A
Flammability	N/A
Vapor Pressure	N/A
Vapor Density	N/A
Relative Density	N/A
Solubility in water	N/A
Auto-ignition Temp	N/A
Decomposition Temp	N/A
Viscosity	3-6 million cps

Section X – STABILITY AND REACTIVITY

Stability:	Stable under recommended storage conditions.
Reactivity:	No data available.
Incompatible Material:	Strong bases, strong oxidizing agents.
Conditions to Avoid:	Direct sunlight. May polymerize on exposure to light. Extreme high or low temperatures.
Hazardous Decomposition Products:	Hazardous decomposition products formed under fire conditions. Oxides of carbon and nitrogen when burned. Other decomposition products – no data available.

Section XI – TOXICOLOGICAL INFORMATION

Acute toxicity

Individual components:

Ingredient	Toxicology Data
Bis-GMA	Not classified – no animal test data available, high viscosity
Urethane dimethacrylate	LD50 Oral (Rat): > 5,000 mg/kg
Triethylene glycol dimethacrylate	LD50 Oral (Rat): 10,837 mg/kg; LD50 Dermal (Mouse): > 2,000 mg/kg
Butylated hydroxytoluene	LD50 Oral (Rat): > 6,000 mg/kg; LD50 Dermal (Rat): > 2,000 mg/kg

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Section XII – ECOLOGICAL INFORMATION

Toxicity

Bis-GMA: No data available, high viscosity.

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)

Triethylene glycol dimethacrylate

Toxicity to zebra fish (<i>Danio rerio</i>), semi-static test LC50	16.4 mg/l (96 h)
Toxicity to green algae (<i>Pseudokirchneriella subcapitata</i>), growth inhibition EC50	72.8 mg/l (72 h)

Urethane dimethacrylate

Toxicity to water flea (<i>Daphnia magna</i>), static test EC50	> 1.2 mg/l (48 h)
Toxicity to green algae (<i>Desmodesmus subspicatus</i>), static test EC50	> 0.6 mg/l (72 h)

Persistence and degradability

Bis-GMA: No data available

Urethane dimethacrylate: Biodegradability aerobic – Exposure time 28 days
Result: 22% - Not readily biodegradable

Triethylene glycol dimethacrylate: Biodegradability aerobic – Exposure time 28 days
Result: 85% - Readily biodegradable

Butylated hydroxytoluene: No data available

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.

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 – Acute health hazard, reactive hazard

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.

Massachusetts Right to Know Components:

	<u>CAS No.</u>	<u>Revision Date</u>
2,6-di-tert-Butyl-p-cresol	128-37-0	1993-04-24

Pennsylvania Right to Know Components:

	<u>CAS No.</u>	<u>Revision Date</u>
Diurethane dimethacrylate	72869-86-4	
2,2'-Ethylenedioxydiethyl dimethacrylate	109-16-0	
2,6-di-tert-Butyl-p-cresol	128-37-0	1993-04-24

New Jersey Right to Know Components:

	<u>CAS No.</u>	<u>Revision Date</u>
Diurethane dimethacrylate	72869-86-4	
2,2'-Ethylenedioxydiethyl dimethacrylate	109-16-0	
2,6-di-tert-Butyl-p-cresol	128-37-0	1993-04-24

California Prop. 65 Components:

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

NFPA Rating:

Health hazard:	2	Short exposure could cause serious temporary or residual injury even though prompt medical attention was given.
Fire hazard:	1	Materials that require preheating before ignition/combustion can occur.
Reactivity hazard:	0	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 Acute 3	Acute aquatic toxicity Category 3
Aquatic Chronic 1	Chronic aquatic toxicity Category 1
Aquatic Chronic 3	Chronic aquatic toxicity Category 3
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H400	Very toxic to aquatic life
H402	Harmful to aquatic life
H410	Very toxic to aquatic life with long lasting effects
H412	Harmful 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