


Trade Name: **PULPDENT Orthodontic Bracket Adhesive (OBA)**

1.0 Commercial Product Name and Supplier			
1.1	Commercial product name / designation	Ortho-Choice™ Orthodontic Bracket Adhesive (OBA)	
1.2	Application / Use	Dental material for use by dental professional only.	
1.2.2	SIC	851 Human health activity	
1.2.3	Use Category	55	
1.3	Manufacturer	Telephone: 1 617 926-6666 / Fax: 1 617 926-6262	
	Pulpdent Corporation	Email: Pulpdent@pulpdent.com	
	80 Oakland Street, P.O. Box 780		
	Watertown, MA 02472 USA		
1.4	Emergency Number	24 Hour Emergency: 1-800-535-5053 (USA)	
1.5	Authorized European Representative	Advena Ltd.	
		Pure Offices, Plato Close	
		Warwick, CV34 6WE	
		United Kingdom	
2.0 Hazards Identification			
2.1	Classification	Irritant.	
2.1.1	Classification according to Regulation (EC) No 1272/2008 [CLP]	<u>Hazard Class</u>	<u>Hazard Category</u>
			<u>Hazard Statement</u>
		Eye irritation	2
		STOT SE	3
		Skin irritation	2
		Skin sensitization	1
			H319
			H335
			H315
			H317
2.1.2	Classification according to Directive 67/548/EEC (See SECTION 16 for full text of risk phrases)	Xi (Irritant); R 36/37/38 - 43	
2.2	GHS Label Elements		
	Hazard Pictograms		
			
	Signal Word: WARNING		
	Restricted to use by dental professional only.		
	Hazard Statements		
	H319: Eye irritation. 2. May cause eye irritation.		
	H335: STOT SE. 3. May cause respiratory irritation.		
	H315: Skin irritation. 2. May cause skin irritation.		
	H317: Sensitization. 1. May cause an allergic skin reaction.		
	Precautionary Statements		
	P261: Avoid breathing vapor.		
	P280: Wear protective gloves and eye protection		
	P305+P351: If in eyes, rinse cautiously with water for several minutes.		
	P337+P313: If eye irritation persists, get medical advice/attention.		
	P302+P352: If on skin, wash with plenty of soap and water.		
	P333+P313: If irritation or rash occurs, get medical advice/attention.		
	P410+P411: Protect from sunlight. Store at temperature not exceeding 27°C / 80°F.		

Trade Name: **PULPDENT Orthodontic Bracket Adhesive (OBA)**

3.0	Composition				
3.1	Chemical characterization of the preparation		Glass filler in light-cured aromatic / aliphatic methacrylate resins.		
3.2	Hazardous ingredients				
	CAS Number	Name of the Ingredient	Concentration	Classification per 67/548/EEC	Classification per Regulation (EC) No.1272/2008 (CLP)
	Proprietary	Mixture of uncured methacrylate ester monomers	55-65%	Xi (Irritant), R36/37/38; R43	Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Skin sensitization, 1, H317
	112945-52-5	Amorphous silica	5.0 %	Xi (Irritant), R36/37/38	Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315
4.0	First Aid Measures				
4.1	General Information		May be irritating to eyes, respiratory system and skin. Do not inhale vapors. May cause sensitization by skin contact. Show this safety data sheet to medical personnel. Seek medical attention in case of uncertainty.		
4.2	Inhalation		Move to fresh air. If necessary, administer oxygen, artificial respiration and seek medical attention.		
4.3	Skin Contact		Take off contaminated clothing. Wash skin thoroughly with soap and running water for 15 minutes.		
4.4	Eye Contact		Keep eyelids apart, flush with running water for 15+ minutes. Seek medical attention.		
4.5	Ingestion		Rinse mouth with water. Do not induce vomiting. Seek immediate medical attention. May be irritating to mucous membranes.		
4.6	Precautions for first responders		Ventilate the area. Wear eye and skin protection.		
4.7	Information for physicians				
	Symptoms		Irritation or redness in eyes, throat or on skin.		
	Hazards		May be irritating to eyes, respiratory system and skin. May cause sensitization by skin contact.		
	Treatment		As above under First Aid.		
5.0	Fire Fighting Measures				
5.1	Suitable extinguishing media		Carbon dioxide, dry chemical, alcohol foam, or water fog. Water spray may be used to keep fire exposed containers cool.		
5.2	Extinguishing media to avoid		Do not use direct water stream		
5.3	Special exposure hazards in a fire		Heat of fire may cause polymerization with rapid release of energy, especially in amounts greater than in this product.		
5.4	Special protective equipment for fire-fighters		Self-contained breathing apparatus.		
6.0	Accidental Release Measures				
6.1	Personal precautions.		Ventilate area. Wear safety glasses, gloves, and lab coat.		

Trade Name: **PULPDENT Orthodontic Bracket Adhesive (OBA)**

6.2	Environmental precautions	Contain uncured, spilled material. Cured/set-up material is, to our knowledge, inert. Follow all government regulations.
6.3	Method for clean up	Wipe up spill with paper towels or cloths. Collect for disposal in a covered container. Wash area of spill with alcohol or soap and water.

7.0 Handling and Storage

7.1	Handling	For use only by dental professionals trained in its use. Follow good hygiene practices. Remove applicator tip from syringe and recap immediately after use. Keep light cure materials shaded from intense light sources.
7.2	Storage	Store in tightly capped original container at cool room temperature (<25°C). Avoid direct, intense light, sources of ignition, extremes of temperature (>80°F/27°C, <40°F/ 5°C). Shelf life for unopened product is two years from date of manufacture, provided that the material has been stored properly.
7.3	Specific uses	Dental material

8.0 Exposure Controls / Personal Protection

8.1	Exposure limit values	PEL: Not established. TLV: Not established.
8.2	Exposure controls	
8.2.1	Occupational exposure controls	No special equipment required under normal conditions of use
8.2.1.1	Respiratory protection	Good general ventilation is sufficient to control any airborne.
8.2.1.2	Hand protection	Protective gloves are recommended.
8.2.1.3	Eye protection	Safety glasses are recommended
8.2.1.4	Skin protection	Good personal hygiene and safety practices; wear a lab coat.
8.2.1.5	Other controls	Emergency eye wash fountain should be available. Wash hands after use.
8.2.2	Environmental exposure controls	Cure material before disposing.

9.0 Physical and Chemical Properties

9.1	Characteristics	
9.1.1	Appearance / Color / Physical state	Stiff off-white paste
9.1.2	Odor	Faint, characteristic
9.2	Important health, safety and environmental information	
9.2.1	pH	Not determined
9.2.2	Boiling point	Not determined
9.2.3	Flash point	Not determined
9.2.4	Flammability (solid, gas)	Not applicable
9.2.5	Explosive properties	Not applicable
9.2.6	Oxidizing properties	Not determined
9.2.7	Vapor pressure	< 1 mm Hg / 133 Pa / Id: B
9.2.8	Specific gravity	1.820
9.2.9	Solubility in water	Nil

Trade Name: **PULPDENT Orthodontic Bracket Adhesive (OBA)**

9.2.10	Partition coefficient	Not determined
9.2.11	Viscosity	Not determined
9.2.12	Vapor density	1
9.2.13	Evaporation rate	< 0.1

10.0 Stability and reactivity

10.1	Conditions to avoid	Temperature > 80°F/27°C, strong visible light.
10.2	Materials to avoid	Reducing and oxidizing agents, peroxides, amines.
10.3	Hazardous decomposition products	Under fire conditions and with amounts far greater than that supplied in this product, hazardous polymerization may occur with heat build up and release of carbon monoxide, carbon dioxide, and oxides of nitrogen.
10.4	Further information	Stable if stored and used as directed. Polymerization will occur when light-cured material is exposed to direct light.

11.0 Toxicological information

11.1	Acute toxicity	Not toxic. Minimal health hazard in the quantities present in this product and under normal conditions of use.
11.2	Irritation and corrosiveness	May be irritating to eyes, mucous membranes or skin on contact or with prolonged exposure.
11.3	Sensitization	May be sensitizing. Prolonged or frequent skin contact may cause allergic skin reactions in some susceptible individuals.
11.4	Sub-acute, sub-chronic and prolonged toxicity	Prolonged and/or frequent skin contact may cause allergic skin reactions in susceptible individuals. Prolonged exposure to large amounts (more than in this product) of this material may cause eye and respiratory irritation.
11.5	Carcinogenicity, Mutagenicity, Reproductive Toxicity	None known
11.6	Empirical data	Not available
11.7	Clinical experience	OBA has been used by dental professionals for over 20 years. During that time there have been no significant complaints regarding safety or effectiveness, no recalls and no adverse events.

12.0 Ecological Information

12.1	Eco-toxicity	Avoid release of uncured material into the environment. To the best of our knowledge, polymerized material is inert. No other information is available. Follow all government regulations.
------	--------------	--

13.0 Disposal Considerations

13.1	Regulations	Follow all local and national government regulations in disposing material or contaminated packaging.
------	-------------	---

14.0 Transport Information

14.1	Restrictions	None. Not regulated.
------	--------------	----------------------

Trade Name: **PULPDENT Orthodontic Bracket Adhesive (OBA)**

15.0 Regulatory Information		
15.1	EU Regulations	Class IIa medical device under MDD 93/42/EEC.
15.2	US FDA	Class II medical device
15.3	Health Canada	Class II medical device
16.0 Other information		
16.1	List of relevant R phrases	R36/37/38, Irritating to eyes, respiratory system and skin. R43, Sensitizing by skin contact.
16.2	Hazard Statements	H319: Eye irritation. Hazard category 2. H335: Specific Target Organ Toxicity - Single exposure. Hazard category 3. Respiratory tract irritation. H315: Skin irritation. Hazard category 2. H317: Skin Sensitization. Hazard category 1.
16.3	Precautionary Statements	P261: Avoid breathing vapor. P280: Wear protective gloves and eye protection P305 + P351: If in eyes, rinse cautiously with water for several minutes. P337 + P313: If eye irritation persists, get medical advice/attention. P302 + P352: If on skin, wash with plenty of soap and water. P333 + P313: If irritation or rash occurs, get medical advice / attention. P410 + P411: Protect from sunlight. Store at temperature not exceeding 27°C / 80°F.
16.4	Restrictions on use	Pulpdent products are to be sold to and used by dental professionals only.
16.5	Further information	The information presented herein is believed to be factual as it has been derived from the works of persons believed to be qualified experts. However, nothing contained in this information is to be taken as a warranty or representation for which Pulpdent Corporation bears legal responsibility. The user should review any recommendations in the specific context of the intended use to determine whether they are appropriate.
16.6	Sources of key data	National Institute for Occupational Safety (NIOSH) US Occupational Safety and Health Administration (OSHA) Eur-Lex European Union Law: Regulation (EC) No. 1272/2008 (CLP) and Regulation (EC) No. 1907/2006 (REACH). Guidance on the compilation of safety data sheets. Version 1.1; December 2011. European Chemicals Agency
16.7	Information which has been added, deleted or revised.	This Safety Data Sheet has been revised to meet the requirements of the GHS SDS format, Regulations (EC) No. 1272/2008 (CLP) and (EC) No. 1907/2006 (REACH). Specifically, Sections 2.1, 2.2, 3.2, 16.2, 16.3 have been modified.