


Safety Data Sheet

Trade Name: *Ortho-Choice Band-Rite™*

1.0 Commercial Product Name and Supplier			
1.1	Commercial product name / designation	Ortho-Choice Band-Rite™	
1.2	Application / Use	Orthodontic adhesive for use by dental professional only.	
1.2.2	SIC	851 Human health activity	
1.2.3	Use Category	55	
1.3	Manufacturer	Pulpdent Corporation 80 Oakland Street, P.O. Box 780 Watertown, MA 02472 USA Telephone: 1 617 926-6666 / Fax: 1 617 926-6262 Email: Pulpdent@pulpdent.com	
1.4	Emergency Telephone Number	1-800-535-5053 (24 Hour / USA)	
1.5	Authorized European Representative	Advena Ltd. Pure Offices, Plato Close Warwick, CV34 6WE United Kingdom	
2.0 Hazards Identification			
2.1	Classification		
2.11	Classification according to Regulation (EC) No 1272/2008 [CLP]	<u>Hazard Class</u> Eye irritation STOT SE Skin irritation Skin sensitization	<u>Hazard Category</u> 2 3 2 1 <u>Hazard Statement</u> H319 H335 H315 H317
2.1.2	Classification according to Directive 67/548/EEC	Irritant; Xi; R 36/37/38 – 43 (See SECTION 16 for full text of risk phrases)	
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.		

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3.0	Composition				
3.1	Chemical characterization of the preparation: Dual-cure, resin-based orthodontic cement in two parts.				
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	30-35%	Irritant; Xi R 3637//38 - 43	Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Skin sensitization, 1, H317
	112945-52-5	Amorphous, fumed silica	1.0%	Irritant; Xi, R 36/37/38	Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315
4.0	First Aid Measures				
4.1	Special Instructions	Avoid contact. 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. Get medical attention in case of uncertainty.			
4.2	Inhalation	Move to fresh air. Administer artificial respiration as needed; seek medical attention.			
4.3	Skin Contact	Take off contaminated clothing. Wash skin thoroughly with soap and water.			
4.4	Eye Contact	Keep eyelids apart; flush with running water for 15+ minutes. Get medical attention.			
4.5	Ingestion	Rinse mouth with water. Do not induce vomiting. Get immediate medical attention. May be irritating to mucous membranes. Never give anything by mouth to an unconscious person			
4.6	Precautions for first responders	Wear gloves to prevent skin contact and safety glasses if splash is a possibility.			
4.7	Information for physician				
	Symptoms	Irritation or redness in eyes and on skin.			
	Hazards	May be irritating to eyes, respiratory system and skin. Possible sensitization with prolonged or repeated skin contact.			
	Treatment	Same 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 may cause polymerization with rapid release of energy.			
5.4	Special protective equipment for fire-fighters	Self-contained breathing apparatus. Cool exposed containers with water spray to prevent polymerization under fire conditions.			
6.0	Accidental Release Measures				
6.1	Personal precautions.	Ventilate area. Wear gloves, lab coat and safety glasses.			
6.2	Environmental precautions	Contain spilled material. Follow all government regulations			

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6.3 Method for clean up Wipe up spill with suitable material (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. Follow good hygiene practices. Do not smoke, eat or drink while using. Cap product immediately after use. Keep light-cured materials shaded from intense light. Not an aerosol or dust hazard.

7.2 Storage Store product tightly capped in original container at cool room temperature (<25°C). Avoid direct, strong light, sources of ignition, extremes of temperature (>27°C/80°F, <5°C/40°F). 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 Not established

8.2 Exposure controls

8.2.1 Occupational exposure controls No special equipment required under normal conditions of use of this product in the quantity provided.

8.2.1.1 Respiratory protection None required. Good general ventilation is sufficient to control airborne vapors.

8.2.1.2 Hand protection No special requirements other than the usual surgical gloves.

8.2.1.3 Eye protection No special requirements other than the usual safety glasses.

8.2.1.4 Skin protection No special requirements. Good personal hygiene, safety practices and wearing a lab coat should protect from exposure to uncured material.

8.2.1.5 Other controls Emergency eye wash fountain should be close by. 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	<u>Base</u>	<u>Catalyst</u>
	Pale yellow thick paste	Yellow-gray thick 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 Not determined

9.2.8 Specific gravity Base: 1.813; Catalyst: 2.000

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9.2.9	Solubility in water	Nil
9.2.10	Partition coefficient	Not determined
9.2.11	Viscosity	Not determined
9.2.12	Vapor density	Not determined
9.2.13	Evaporation rate	Not determined
10.0	Stability and reactivity	
10.1	Conditions to avoid	Temperature > 38°C, light, contamination.
10.2	Materials to avoid	Reducing and oxidizing agents, peroxides, amines.
10.3	Hazardous decomposition products	Under fire conditions and with amounts greater than that supplied in this product, hazardous polymerization may occur with heat build up and release of carbon monoxide, carbon dioxide, oxides of nitrogen.
10.4	Further information	Light-cured material will polymerize if 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.
11.5	Carcinogenicity, Mutagenicity, Reproductive Toxicity	None known
11.6	Empirical data	Not available
11.7	Clinical Experience	Band-Rite has been on the market in the US and internationally for more than 15 years. There have been no reports of adverse events.
12.0	Ecological Information	
12.1	Ecotoxicity	Avoid release of uncured material into the environment. To the best of our knowledge, polymerized material is inert
13.0	Disposal Considerations	
13.1	Regulations	Follow all local and national government regulations in disposing material or contaminated packaging. Cure material before disposing. To the best of our knowledge, polymerized material is inert.
14.0	Transport Information	
14.1	Restrictions	None. Not regulated.

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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	Band-Rite is for use 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
16.6	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.