


Safety Data Sheet

Trade Name: **ORTHO-CHOICE™ ORTHO-COAT™**

1.0 Commercial Product Name and Supplier																		
1.1	Commercial product name / designation	Ortho-Choice Ortho-Coat																
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	<p>Pulpdent Corporation 80 Oakland Street, P.O. Box 780 Watertown, MA 02472 USA</p> <p>Telephone: 1 617 926-6666 / Fax: 1 617 926-6262 Email: Pulpdent@pulpdent.com</p>																
1.4	Emergency Telephone Number	1-800-535-5053 (24 Hour / USA)																
1.5	Authorized European Representative	<p>Advena Limited Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013 Malta</p>																
	UK Responsible Person	<p>Advena Limited Pure Offices, Plato Close Warwick, CV34 6WE United Kingdom</p>																
	CH Authorized Representative	<p>MedEnvoy Switzerland Gotthardstrasse 28, 6302 Zug, Switzerland</p>																
2.0 Hazards Identification																		
2.1	Classification	Irritant.																
2.1.1	Classification according to Regulation (EC) No 1272/2008 [CLP]	<table border="1"> <thead> <tr> <th><u>Hazard Class</u></th> <th><u>Hazard Category</u></th> <th><u>Hazard Statement</u></th> </tr> </thead> <tbody> <tr> <td>Eye irritation</td> <td>2</td> <td>H319</td> </tr> <tr> <td>STOT SE</td> <td>3</td> <td>H335</td> </tr> <tr> <td>Skin irritation</td> <td>2</td> <td>H315</td> </tr> <tr> <td>Skin sensitization</td> <td>1</td> <td>H317</td> </tr> </tbody> </table>	<u>Hazard Class</u>	<u>Hazard Category</u>	<u>Hazard Statement</u>	Eye irritation	2	H319	STOT SE	3	H335	Skin irritation	2	H315	Skin sensitization	1	H317	
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2.1.2	Classification according to Directive 67/548/EEC (See SECTION 16 for full text of risk phrases)	Irritant; Xi; 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.																	

Safety Data Sheet

Trade Name: **ORTHO-CHOICE™ ORTHO-COAT™**

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.

3.0 Composition																					
3.1	Chemical characterization of the preparation: Light cured, acrylate resins																				
3.2	Hazardous ingredients																				
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4.0 First Aid Measures																					
4.1	General Information May be irritating to eyes, respiratory system and skin. Prolonged or repeated contact with acrylate resins may cause sensitization. Show this safety data sheet to medical personnel. Get medical attention in case of uncertainty.																				
4.2	Inhalation Move to fresh air. If necessary, administer oxygen and/or artificial respiration and 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 and 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 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 may cause polymerization with rapid release of energy.																				
5.4	Special protective equipment for fire-fighters Self-contained breathing apparatus should be worn by firefighters.																				

Safety Data SheetTrade Name: **ORTHO-CHOICE™ ORTHO-COAT™**

6.0	Accidental Release Measures	
6.1	Personal precautions.	Ventilate area. Wear safety glasses, gloves and lab coat.
6.2	Environmental precautions	Contain spilled material. Follow all government regulations.
6.3	Method for clean up	Absorb or 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-cured materials shaded from intense light sources.
7.2	Storage	Store product tightly capped in original container at cool room temperature (<25°C). Avoid direct, strong light, sources of ignition, temperature extremes (>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	Silica amorphous: PEL: 6 mg/m ³ . TLV: 10 mg/m ³ Hydrofluoric acid: PEL/TLV: 3 ppm
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 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	Good personal hygiene and safety practices; wearing 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. To the best of our knowledge, cured material is inert. Follow all government regulations.
9.0	Physical and Chemical Properties	
9.1	Characteristics	.
9.1.1	Appearance /Color / Physical state	Clear resin
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

Safety Data Sheet

Trade Name: **ORTHO-CHOICE™ ORTHO-COAT™**

9.2.7	Vapor pressure	< 1 mm Hg / 133 Pa / Id: B
9.2.8	Specific gravity	Not determined
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	> 1
9.2.13	Evaporation rate	Not determined
10.0 Stability and reactivity		
10.1	Conditions to avoid	Temperature extremes (>27°C/80°F, <5°C/40°F), 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 in this product, hazardous polymerization may occur with heat buildup, release of carbon monoxide, carbon dioxide, oxides of nitrogen.
10.4	Further information	Light-cured materials polymerize when 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/frequent skin contact may cause allergic skin reactions in susceptible individuals. Prolonged exposure to amounts greater than in this product may cause eye and respiratory irritation.
11.5	Carcinogenicity, Mutagenicity, Reproductive Toxicity	None known.
11.6	Empirical data	None available.
11.7	Clinical experience	Ortho-Coat been sold on the domestic and international market for more than 8 years with no reports of adverse events.
12.0 Ecological Information		
12.1	Ecotoxicity	To the best of our knowledge, polymerized material is inert. No other information is available.
13.0 Disposal Considerations		
13.1	Regulations	Polymerize before disposal. Follow all local and national government regulations in disposing material or contaminated packaging.
14.0 Transport Information		
14.1	Restrictions	None. Not regulated.
15.0 Regulatory Information		
15.1	EU	Class IIa medical device under MDD 93/42/EEC.
15.2	US FDA	Class II medical device

Safety Data SheetTrade Name: **ORTHO-CHOICE™ ORTHO-COAT™**

15.3	Health Canada	Class III 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 GHS SDS format and 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.