

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

070179366

**The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).**


070179556

## SAFETY DATA SHEET

## 1.0 Commercial Product Name and Supplier

1.1	Commercial product name	<b>ACTIVA BioACTIVE BASE / LINER</b> <b>ACTIVA BioACTIVE-RESTORATIVE</b>
1.2	Application / Use	Dental material for use by dental professional only.
1.2.2	SIC	851 Human health activity
1.3	Use Category	55
1.3.1	Manufacturer, Importer	
1.3.1	Manufacturer	<b>Pulpdent Corporation</b> 80 Oakland Street P.O. Box 780 Watertown, MA 02472 USA 1-800-535-5053 (24 Hour / USA) Advena Ltd. Pure Offices, Plato Close Warwick CV34 6WE UK
1.4	Emergency Telephone Number	Telephone: 1 617 926-6666
1.5	Authorized European Representative	Fax: 1 617 926-6262 Email: Pulpdent@pulpdent.com

## 2.0 Hazards Identification

2.1	Classification	
2.1.1	Classification according to Regulation (EC) No 1272/2008 [CLP]	
	<u>Hazard Class</u>	<u>Hazard Category</u>
	Eye irritation	2
	STOT SE	3
	Skin irritation	2
	Skin sensitization	1
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: <b>WARNING</b>	

**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.

## 3.0 Composition

3.1	Chemical characterization of the preparation:			Resin-modified glass ionomer dental material		
3.2	Hazardous ingredients					
	CAS Number	Name of the Ingredient	Concentration BASE/LINER	Concentration RESTORATIVE	Classification per 67/548/EEC	Classification per Regulation (EC) No.1278/2008 (CLP)
	Proprietary	Blend of diurethane and other methacrylates with modified polyacrylic acid	53.2%	44.6%	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	Silica, amorphous	3.0%	6.7%	Irritant; Xi, R 36/37/38	Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315
	7681-49-4	Sodium fluoride	0.90%	0.75%	Harmful (Xn); R22-36/38	Acute toxicity, 4, H302 Skin irritation, 2, H315 Eye irritation, 2, H319

## 4.0 First Aid Measures

4.1	General Information	May be irritating to eyes, respiratory system and skin. Avoid contact with eyes 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. If necessary, administer oxygen and/or artificial respiration. 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	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	A self-contained breathing apparatus should be worn by firefighting personnel. Cool exposed containers with water spray to prevent polymerization under fire conditions.

## 6.0 Accidental Release Measures

6.1	Personal precautions.	Wear safety glasses, gloves and lab coat.
6.2	Environmental precautions	Avoid releasing large amounts of uncured material into the environment. Cured / set-up material is, to our knowledge, inert.
6.3	Method for clean up	Contain spilled material. Absorb or 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. Avoid direct / strong light sources, extremes of temperature (>27°C/80°F, <5°C/40°F), contamination, cross contamination of two-part materials. Recap immediately after use.
7.2	Storage	Keep container tightly closed. Store product in original container at cool room temperature (<25°C) and in a dry, well-ventilated area. Avoid direct, strong light, sources of ignition and extremes of temperature. 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 base/liner, cement or restorative

## 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 of this product in the quantity provided.

8.2.1.1	Respiratory protection	None required. Good general ventilation is sufficient to control any airborne vapors from uncured material.			
8.2.1.2	Hand protection	No special requirements. The usual surgical gloves worn by dental staff will limit contact with uncured material.			
8.2.1.3	Eye protection	No special requirements other than the usual safety glasses worn by dental staff.			
8.2.1.4	Skin protection	No special requirements. Good personal hygiene, safety practices and wearing a lab coat should protect dental staff from unnecessary exposure to uncured material.			
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.			
<b>9.0 Physical and Chemical Properties</b>					
9.1	Appearance / Color	Base / Liner	Two pastes:	Part A	Part B
9.1.1	Physical state / Color	Restorative	Two thick pastes	Yellowish	Off-white
9.1.2	Odor	Faint, characteristic		Tooth-colored	Off-white
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			
9.2.8	Specific gravity		Part A	Part B	
		Base / Liner	1.460 g/mL	1.380 g/mL	
		Restorative	1.580 g/mL	1.620 g/mL	
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			
<b>10.0 Stability and reactivity</b>					
10.1	Conditions to avoid	Temperature > 38°C, intense light, cross-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, and oxides of nitrogen.			
10.4	Further information	Stable material if stored and used as directed. Polymerization will occur when light-cured material is exposed to direct light.			
<b>11.0 Toxicological information</b>					
11.1	Acute toxicity	Finished products in paste form present a minimal health hazard under normal conditions of use and in the quantities necessary for dental procedures. Sodium fluoride: Oral rat LD50: 180 mg/kg Silica, amorphous: Oral rat LD50: 3160 mg/kg			
11.2	Irritation and corrosiveness	May be irritating to eyes, respiratory tract, 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) may cause eye and respiratory irritation.			
11.5	Carcinogenicity, Mutagenicity, Reproductive Toxicity	None known			
11.6	Empirical data	Biocompatibility has been tested and found to be acceptable.			
11.7	Clinical experience	ACTIVA BioACTIVE PRODUCTS are new products that have been evaluated by dentist consultants. There have been no reports of adverse events.			
<b>12.0 Ecological Information</b>					
12.1	Ecotoxicity	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.			
<b>13.0 Disposal Considerations</b>					
13.1	Regulations	Follow all local and national government regulations in disposing material or contaminated packaging.			
<b>14.0 Transport Information</b>					
14.1	Restrictions	None. Not regulated.			
<b>15.0 Regulatory Information</b>					
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 III medical device			
<b>16.0 Other Information</b>					
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	ACTIVA BioACTIVE 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.			

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