SAFETY DATA SHEETS

This SDS packet was issued with item:

075890843

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).

070447458 070447466 070447474 070447482 070447490 070447508 070451393 070451401 070451419 075890702 075890710 075890728 075890736 075890744 075890777 075890785 075890793 075890801 075890819 075890850

Trade	Name: ACTIVA BioACTIVE PR	ODUCTS		
1.0	Commercial Product Name and Su	pplier		
1.1	Commercial product name		IVE-BASE / LINER IVE-RESTORATIVE	
1.2	Application / Use	Dental material fo	r use by dental professiona	l only.
1.2.2	SIC	851 Human healt	h activity	
1.2.3	Use Category	55		
1.3	Manufacturer, Importer			
1.3.1	Manufacturer			
	Pulpdent Corporation 80 Oakland Street P.O. Box 780 Watertown, MA 02472 USA	Telephone: 1 617 Fax: 1 617 Email: <u>Pulpdent@</u>	926-6262	
1.4	Emergency Telephone Number	1-800-535-5053 (24 Hour / USA)	
1.5	Authorized European Representative			
	International Business Solutions Ltd. 54 Mayfield Ridge Hatch Warren, Basingstoke, RG22 4F	Fmail: s williams	9 / Fax: 01256 350330 @btconnect.co.uk	
2.0	Hazards Identification			
2.1	Classification			
2.1.1	Classification according to Regulation (EC) No 1272/2008 [CLP]	Hazard Class Eye irritation STOT SE Skin irritation Skin sensitization	Hazard Category 2 3 2 1	Hazard Statement H319 H335 H315 H317
2.1.2	Classification according to Directive 6 (See SECTION 16 for full text of risk)		R 36/37/38 - 43	
2.2	GHS Label Elements			
	Hazard Pictograms			
	<u>(!</u>)			
	Signal Word: WARNING			

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.

Trade Name: ACTIVA BioACTIVE PRODUCTS

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.

Revision Date: November 1, 2013

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 Ingredie		ient	Concentration BASE/LINER	Concentration RESTORATIVE	Classification per 67/548/EEC	Classification per Regulation (EC) No.1278/2008 (CLP).	
	Proprietary	Blend of diurethane a other methacrylates v modified polyacrylic a	vith	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 Mea	sures						
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. Administer oxygen/CPR 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 fo	or first responders	Ventil	ate the area. We	ar eye and skin p	rotection.		
4.7	Information fo	r physicians			_			
	Symptoms				eyes, throat or or			
	Hazards		May be irritating to eyes, respiratory system, skin. May be sensitizing by skin contact.					
	Treatment		As ab	ove under First	Aid.			
5.0	Fire Fighting							
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 expos	sure hazards in a fire	Hea	at may cause po	lymerization with	rapid release of ene	ergy.	
5.4	Special protection fire-fighters	ctive equipment for	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 R	elease Measures						
6.1	Personal prec	autions.	We	ar safety glasse	s, gloves and lab	coat.		

Trade Name: ACTIVA BioACTIVE PRODUCTS

6.2	Environmental precautions	Avoid releasing large amounts of uncured material into the environment. Cured / se up material is, to our knowledge, inert.				
6.3	Method for clean up	Contain spilled material. Absorb or wipe up spill with suitable material (e.g. pape towels). Collect for disposal in a covered container. Wash area of spill with alcohol c soap and water.				
7.0	Handling and Storage					
7.1	Handling	sources, extremes	For use only by dental professionals. Practice good hygiene. Avoid direct/strong lig 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	(<25°C). Avoid dir	Keep container tightly closed. Store in original container at cool room temperature (<25°C). Avoid direct/strong light, sources of ignition, extremes of temperature. Shell life for properly stored, unopened product is two years from date of manufacture.			
7.3	Specific uses	Dental base/liner,	cement or restorative)		
8.0	Exposure Controls / Personal Pro	tection				
8.1	Exposure limit values	PEL: Not establis	hed. TLV: Not estal	blished.		
8.2	Exposure controls					
8.2.1	Occupational exposure controls		ment required under			
8.2.1.1	Respiratory protection	•	J		trol any airborne vapors.	
8.2.1.2	Hand protection		ements other than th	0 0		
8.2.1.3	Eye protection				es 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 bef	ore disposing.			
9.0	Physical and Chemical Properties					
9.1	Appearance / Color			Part A	Part B	
9.1.1	Physical state / Color	Base / Liner	Two pastes:	Yellowish	Off-white	
		Restorative	Two thick pastes	Tooth-colored	Off-white	
9.1.2	Odor	Faint, characteris	tic			
9.2	Important health, safety and environi	mental information				
9.2.1	рН	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				
	Oxidizing properties	Not determined				
9.2.6	Oxidizing properties					
9.2.6 9.2.7	Vapor pressure	< 1 mm Hg				
		< 1 mm Hg	Part A	Part B		

Trade Name: ACTIVA BioACTIVE PRODUCTS

		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
10.0	Stability and reactivity	
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, amounts greater than that supplied in this product may polymerize with heat build-up, release of oxides of carbon and 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.
11.0	Toxicological information	
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 LD $_{50}$: 180 mg/kg Silica, amorphous: Oral rat LD $_{50}$: 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.
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. 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: ACTIVA BioACTIVE PRODUCTS

15.0	Regulatory Information	
15.1	EU	Class IIA medical devices under MDD 93/42/EEC.
15.2	US FDA	Class II medical devices.
15.3	Health Canada	Class III medical devices
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 / $80^{\circ}F$.
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.

Trade Name: ACTIVA BioACTIVE-BASE / LINER

1.0	Commercial Product Name and Supplier	
1.1	Commercial product name	ACTIVA BioACTIVE-BASE / LINER
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 Pulpdent Corporation 80 Oakland Street, P.O. Box 780 Watertown, MA 02472 USA	Telephone: 1 617 926-6666 / Fax: 1 617 926-6262 Email: <u>Pulpdent@pulpdent.com</u>
1.4	Emergency Telephone Number	1-800-535-5053 (24 Hour / USA)
1.5	Authorized European Representative	Advena Limited Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013 Malta

2.0	Hazards Identification			
2.1	Classification			
2.1.1	Classification according to Regulation (EC) No 1272/2008 [CLP]	Hazard Class	Hazard Category	Hazard Statement
		Eye irritation	2	H319
		STOT SE	3	H335
		Skin irritation	2	H315
		Skin sensitization	1	H317

Irritant; Xi; R 36/37/38 – 43 (See SECTION 16 for full text of risk phrases)

2.2 GHS Label Elements

Hazard Pictograms



2.1.2

Signal Word: WARNING

Restricted to use by dental professional only.

Classification according to Directive 67/548/EEC

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.

Trade Name: ACTIVA BioACTIVE-BASE / LINER

P410+P411: Protect from sunlight. Store at temperature not exceeding 27°C / 80°F.

Revision Date: July 10, 2019

3.0	Composition					
3.1	Chemical character	terization of the preparation:		Bioactive ionic resin with reactive glass filler		ass filler
3.2	Hazardous ingredients					
	CAS Number Name of the Ingredient		Ingredient	Concentration	Classification per 67/548/EEC	Classification per Regulation (EC) No.1272/2008 (CLP).
	Proprietary	Proprietary Blend of diurethane a other methacrylates with modified polyacrylic a		53.2%	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, amorph	nous	3.0%	Irritant; Xi, R 36/37/38	Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315
	7681-49-4	Sodium fluorio	de	0.90%	Harmful (Xn); R22-36/38	Acute toxicity, 4, H302 Skin irritation, 2, H315 Eye irritation, 2, H319
4.0	First Aid Measure	S				
4.1	General Information	General Information May be irritating to eyes, respiratory system and skin. Avoid contact with eyes skin. Do not inhale vapors. May cause sensitization by skin contact. Show this s data sheet to medical personnel. Get medical attention in case of uncertainty.			on by skin contact. Show this safety	
4.2	Inhalation		Move to fre medical atte		ry, administer oxyg	en and/or artificial respiration. Seek
4.3	Skin Contact		Take off co	contaminated clothing. Wash skin thoroughly with soap and water.		
4.4	Eye Contact		Keep eyelid	ls apart; flush with	running water for 1	5+ minutes. Get medical attention.
4.5	Ingestion	Ingestion				g. Get immediate medical attention. er give anything by mouth to an
4.6	Precautions for first	responders	Ventilate the	e area. Wear eye	and skin protection.	
4.7	Information for phys	sicians				
	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 Meas	sures				
5.1	Suitable extinguish	ing media		xide, dry chemical exposed containe		ater fog. Water spray may be used
5.2	Extinguishing media	a to avoid	Do not use	not use direct water stream		
5.3	Special exposure h	azards in a fire	Heat may c	ause polymerizati	on with rapid release	e of energy.
5.4	Special protective equipment for Self-contain fire-fighters		ned breathing appa	aratus		
	- 3					

Trade Name: ACTIVA BioACTIVE-BASE / LINER

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 alcoho or soap and water.
7.0	Handling and Storage	
7.1	Handling	For use only by dental professionals. Follow good hygiene practices. Avoid direct strong light sources, temperature extremes (>27°C/80°F, <5°C/40°F), contamination cross contamination. Recap immediately after use.
7.2	Storage	Store product tightly capped in original container at cool room temperature (<25°C) 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
8.0	Exposure Controls / Personal Pro	tection
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 vapors.
8.2.1.2	Hand protection	No special requirements other than the usual surgical gloves worn by dental staff.
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	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.
9.0	Physical and Chemical Properties	
9.1	Characteristics	
9.1.1	Appearance /Color / Physical state	Two pastes: Part A is yellowish; Part B is off-white
9.1.2	Odor	Faint, characteristic
9.2	Important health, safety and environr	mental information
9.2.1	рН	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
J.Z.1	' '	-

14.1

Restrictions

Safet	Safety Data Sheet				
Trade I	Name: ACTIVA BioACTIVE-BA	SE / LINER			
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, 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.			
11.0	Toxicological information				
11.1	Acute toxicity	Finished product in paste form presents a minimal health hazard under normal conditions of use and in the quantities necessary for dental restoration. Sodium fluoride: Oral rat LD ₅₀ : 180 mg/kg Silica, amorphous: Oral rat LD ₅₀ : 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 Base/Liner is a new product that has been evaluated by dentist consultants. 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. 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				

Revision Date: July 10, 2019

None. Not regulated.

Trade Name: ACTIVA BioACTIVE-BASE / LINER

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 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 ≤ 27°C / 80°F.
16.4	Restrictions on use	Activa Base/Liner is 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.

Revision Date: July 10, 2019