SAFETY DATA SHEETS

This SDS packet was issued with item:

070179556

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

070179366

Trade Name: ACTIVA BioACTIVE-RESTORATIVE

1.0	Commercial Product Name and Sup	plier			
1.1	Commercial product name	ACTIVA Bio	ACTIVE-RESTORATIVE		
1.2	Application / Use	Dental material f	or use by dental professional	only.	
1.2.2	SIC	851 Human heal	th 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 61 Email: <u>Pulpdent(</u>	7 926-6666 / Fax: 1 617 926-6 <u>Opulpdent.com</u>	3262	
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 4RS UK		Tel: 07989 407479 / Fax: 01256 350330 Email: <u>s.williams5@btconnect.com</u>		
2.0	Hazards Identification				
2.1	Classification				
2.1.1	Classification according to	Hazard Class	Hazard Category	Hazard Statement	
	Regulation (EC) No 1272/2008 [CLP]	Eye irritation STOT SE Skin irritation Skin sensitization	2 3 2 1	H319 H335 H315 H317	
2.1.2	Classification according to Directive 67	7/548/EEC Irritant; Xi; R	36/37/38 – 43 (See SECTION 1	6 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.

3.0	Composition						
3.1	Chemical characteri	zation of the pre	paration:	Bioactive ionic resin with reactive glass filler			
3.2	Hazardous ingredients						
	CAS Number	Name of the	Ingredient	Concentration	Classification per 67/548/EEC	Classification per Regulation (EC) No.1278/2008 (CLP).	
	Proprietary	Blend of diure other methacr modified polya	ylates with	44.6%	Irritant; Xi R 3637//38 - 43	Eye irritation, 2 STOT SE 3 Skin irritation, 2 Skin sensitization, 1	
	112945-52-5	Silica, amorph	ous	6.7%	Irritant; Xi, R 36/37/38	Eye irritation, 2 STOT SE 3 Skin irritation, 2	
	7681-49-4	Sodium fluorid	le	0.75%	Harmful (Xn); R22-36/38	Acute toxicity, 4 Skin irritation, 2 Eye irritation, 2	
4.0	First Aid Measures	5					
4.1	skin. D			irritating to eyes, respiratory system and skin. Avoid contact with eyes and not inhale vapors. May cause sensitization by skin contact. Show this safety set 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 co	ntaminated clothin	g. Wash skin thorou	ighly with soap and water.	
4.4	Eye Contact		Keep eyelic	ls apart; flush with	running water for 1	5+ minutes. Get medical attention.	
4.5	Ingestion			itating to mucous		g. Get immediate medical attention. er give anything by mouth to an	
4.6	Precautions for first	responders	Ventilate th	e area. Wear eye	and skin protection.		
4.7	Information for phys	sicians	1.26.0				
	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 u	nder First Aid.			
5.0	Fire Fighting Meas	sures					
5.1	Suitable extinguishi	ng 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	a to avoid	Do not use	direct water stream	m		
5.3	Special exposure ha	azards in a fire	Heat may c	ause polymerizati	on with rapid release	e of energy.	
5.4	Special protective e fire-fighters	quipment for	Self-contair	ned breathing appa	aratus		
6.0	Accidental Releas	e Measures					
6.1	Personal precaution	is.	Wear safety	y glasses, gloves a	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/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. 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 in tightly capped 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 restorative material
8.0	Exposure Controls / Personal Prot	ection
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.
9.0	Physical and Chemical Properties	
9.1	Characteristics	
9.1.1	Appearance /Color / Physical state	Part A: Thick, tooth-colored paste. Part B: Thick, off-white paste.
9.1.2	Odor	Faint, characteristic
9.2	Important health, safety and environn	nental 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
9.2.8	Specific gravity	Part A: 1.580 ± 0.02 g/mL; Part B: 1.620 ± 0.02 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 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 Restorative 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				
14.1	Restrictions	None. Not regulated.			
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	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.			

40	SAFETY DATA S	SHEET					
1.0		duct Name and Supr	olier				
1.1	Commercial produ		110-7-14-15	CTIVE BASE / LINE	R		
1.2	Application / Use			CTIVE-RESTORATI If for use by dental pro-			
1.2.2	SIC		851 Human he		oressional only.		
.3	Use Category Manufacturer, Imp	orter	55				
1.3.1	Manufacturer		Pulpdent Corp		SELVI SE		
			80 Oakland Str P.O. Box 780	reet	Telephone Fax: 1 617	1 617 926-6666	
			Watertown, MA			odent@pulpdent.com	
1.4	Emergency Teleph Authorized Europe	hone Number ean Representative	1-800-535-505 Advena Ltd.	3 (24 Hour / USA)			
1.0	/ lationzed Europe	Sarriopresentative	Pure Offices, P				
2.0	Hansada Idaalif		Warwick CV34	6WE UK			
2.0	Hazards Identific Classification	cation					
2.1.1	Classification acco	ording to Regulation (Et		[CLP]			
	Hazard Class Eye irritation	Haza 2	rd Category		Hazard Statement H319		
	STOT SE	3			H335		
	Skin irritation Skin sensitization	2			H315 H317		
2.1.2	Classification acc	ording to Directive 67/		nt; Xi; R 36/37/38 -			
2.2	(See SECTION 16 GHS Label Eleme	6 for full text of risk phra	ases)				
	Hazard Pictograms	s !!					
	Signal Word: WAI Restricted to use	RNING by dental profession	ial only				
	Hazard Statemen	ts	170.00				
		 n. 2. May cause eye irr 3. May cause respirator 					
	H315: Skin irritatio	n. 2. May cause skin ir	ritation.				
	Precautionary Sta	n. 1. May cause an alle atements	ergic skin reaction	n.			
	P261: Avoid breatl	hing vapor.	COLUMN TO MATERIA				
		ctive gloves and eye pr eyes, rinse cautiously w		eral minutes			
	P337+P313: If eye	irritation persists, get	medical advice/a	attention.			
		skin, wash with plenty ation or rash occurs, ge					
		ect from sunlight. Store			80°F.		
3.0	Composition	deales of the second				Dania madified along inner	was deated motocial
3.1		Chemical characterization of the preparation: Hazardous ingredients		Resin-modified glass ionomer dental material			
	CAS Number	Name of the Ingre	dient	Concentration	Concentration	Classification per	Classification per
		Name of the Ingre-		Concentration BASE/LINER 53.2%	RESTORATIVE	Classification per 67/548/EEC Irritant; Xi	Classification per Regulation (EC) No.1278/2008 (CLP) Eye irritation, 2, H319
	CAS Number Proprietary	Blend of diurethan other methacrylate	e and es with	BASE/LINER		67/548/EEC	Regulation (EC) No.1278/2008 (CLP) Eye irritation, 2, H319 STOT SE 3, H335
		Blend of diurethan	e and es with	BASE/LINER	RESTORATIVE	67/548/EEC Irritant; Xi	Regulation (EC) No.1278/2008 (CLP) Eye irritation, 2, H319
		Blend of diurethan other methacrylate	e and es with ic acid	BASE/LINER	RESTORATIVE	67/548/EEC Irritant; Xi R 3637//38 - 43 Irritant; Xi,	Regulation (EC) No.1278/2008 (CLP) Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Skin sensitization, 1, H317 Eye irritation, 2, H319
	Proprietary	Blend of diurethan other methacrylate modified polyacryl Silica, amorphous	e and es with ic acid	BASE/LINER 53.2% 3.0%	RESTORATIVE 44.6% 6.7%	67/548/EEC Irritant; Xi R 3637//38 - 43 Irritant; Xi, R 36/37/38	Regulation (EC) No.1278/2008 (CLP) Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Skin sensitization, 1, H317 Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315
	Proprietary	Blend of diurethan other methacrylate modified polyacryl	e and es with ic acid	BASE/LINER 53.2%	RESTORATIVE 44.6%	67/548/EEC Irritant; Xi R 3637//38 - 43 Irritant; Xi, R 36/37/38 Harmful (Xn);	Regulation (EC) No.1278/2008 (CLP) Eye imitation, 2, H319 STOT SE 3, H335 Skin imitation, 2, H315 Skin sensitization, 1, H317 Eye imitation, 2, H319 STOT SE 3, H335 Skin imitation, 2, H315 Acute toxicity, 4, H302
	Proprietary 112945-52-5	Blend of diurethan other methacrylate modified polyacryl Silica, amorphous	e and es with ic acid	BASE/LINER 53.2% 3.0%	RESTORATIVE 44.6% 6.7%	67/548/EEC Irritant; Xi R 3637//38 - 43 Irritant; Xi, R 36/37/38	Regulation (EC) No.1278/2008 (CLP) Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Skin sensitization, 1, H317 Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315
4.0	Proprietary 112945-52-5	Blend of diurethan other methacrylate modified polyacryl Silica, amorphous Sodium fluoride	e and as with ic acid	BASE/LINER 53.2% 3.0% 0.90%	RESTORATIVE 44.6% 6.7% 0.75%	67/548/EEC Irritant; Xi R 3637//38 - 43 Irritant; Xi, R 36/37/38 Harmful (Xn); R22-36/38	Regulation (EC) No.1278/2008 (CLP) Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Skin sensitization, 1, H317 Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Acute toxicity, 4, H302 Skin irritation, 2, H315 Eye irritation, 2, H315 Eye irritation, 2, H319
4.0	Proprietary 112945-52-5 7681-49-4	Blend of diurethan other methacrylate modified polyacryll Silica, amorphous Sodium fluoride	e and as with ic acid	BASE/LINER 53.2% 3.0% 0.90%	RESTORATIVE 44.6% 6.7% 0.75%	67/548/EEC Irritant; Xi R 3637//38 - 43 Irritant; Xi, R 36/37/38 Harmful (Xn): R22-36/38	Regulation (EC) No.1278/2008 (CLP) Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Skin sensitization, 1, H317 Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Acute toxicity, 4, H302 Skin irritation, 2, H315 Eye irritation, 2, H315 Do not inhale vapors. May cause
	Proprietary 112945-52-5 7681-49-4 First Aid Measur	Blend of diurethan other methacrylate modified polyacryll Silica, amorphous Sodium fluoride	e and es with color acid May be irritatin sensitization by	BASE/LINER 53.2% 3.0% 0.90% og to eyes, respirator y skin contact. Show	RESTORATIVE 44.6% 6.7% 0.75%	67/548/EEC Irritant; Xi R 3637//38 - 43 Irritant; Xi, R 36/37/38 Harmful (Xn); R22-36/38	Regulation (EC) No.1278/2008 (CLP) Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Skin sensitization, 1, H317 Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Acute toxicity, 4, H302 Skin irritation, 2, H315 Eye irritation, 2, H315 Eye irritation, 2, H319 Do not inhale vapors. May cause dical attention in case of uncertainty.
4.1 4.2 4.3	Proprietary 112945-52-5 7681-49-4 First Aid Measur General Information Inhalation Skin Contact	Blend of diurethan other methacrylate modified polyacryll Silica, amorphous Sodium fluoride	e and so with to acid May be imitating sensitization by Move to fresh Take off contains	BASE/LINER 53.2% 3.0% 0.90% g to eyes, respirator y skin contact. Show air. If necessary, adminated clothing. We	RESTORATIVE 44.6% 6.7% 0.75% v system and skin. Avoid conthis safety data sheet to minister oxygen and/or artifish skin thoroughly with soa	67/548/EEC Irritant; Xi R 3637//38 - 43 Irritant; Xi, R 36/37//38 Harmful (Xn): R22-36/38 contact with eyes and skin. edical personnel. Get medical respiration. Seek mediap and water.	Regulation (EC) No.1278/2008 (CLP) Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Skin sensitization, 1, H317 Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Acute toxicity, 4, H302 Skin irritation, 2, H315 Eye irritation, 2, H315 Eye irritation, 2, H319 Do not inhale vapors. May cause dical attention in case of uncertainty.
4.1 4.2	Proprietary 112945-52-5 7681-49-4 First Aid Measur General Information	Blend of diurethan other methacrylate modified polyacryll Silica, amorphous Sodium fluoride	May be irritatin sensitization by Move to fresh Take off contar	BASE/LINER 53.2% 3.0% 0.90% g to eyes, respirator y skin contact. Show air. If necessary, adminated clothing. Wa	RESTORATIVE 44.6% 6.7% 0.75% y system and skin. Avoid or this safety data sheet to m ininister oxygen and/or artificials skin thoroughly with soang water for 15+ minutes. C	67/548/EEC Irritant; Xi, R 3637//38 - 43 Irritant; Xi, R 36/37/38 Harmful (Xn): R22-36/38 contact with eyes and skin. edical personnel. Get medical respiration. Seek med ap and water. Get medical attention.	Regulation (EC) No.1278/2008 (CLP) Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Skin sensitization, 1, H317 Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Acute toxicity, 4, H302 Skin irritation, 2, H315 Eye irritation, 2, H315 Eye irritation, 2, H319 Do not inhale vapors. May cause dical attention in case of uncertainty.
4.1 4.2 4.3 4.4 4.5	Proprietary 112945-52-5 7681-49-4 First Aid Measur General Information Inhalation Skin Contact Eye Contact Ingestion	Blend of diurethan other methacrylate modified polyacryli Silica, amorphous Sodium fluoride	May be irritatin sensitization by Move to fresh Take off contar Keep eyelids a Rinse mouth w give anything t	BASE/LINER 53.2% 3.0% 0.90% g to eyes, respirator y skin contact. Show air. If necessary, adr minated clothing. We apart; flush with runni with water. Do not ind by mouth to an uncoi	RESTORATIVE 44.6% 6.7% 0.75% y system and skin. Avoid or this safety data sheet to minister oxygen and/or artificials skin thoroughly with song water for 15+ minutes. Que vomitting. Get immedianscious person.	67/548/EEC Irritant; Xi, R 3637//38 - 43 Irritant; Xi, R 36/37/38 Harmful (Xn): R22-36/38 contact with eyes and skin. edical personnel. Get medical respiration. Seek med ap and water. Get medical attention.	Regulation (EC) No.1278/2008 (CLP) Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Skin sensitization, 1, H317 Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Acute toxicity, 4, H302 Skin irritation, 2, H315 Eye irritation, 2, H315 Eye irritation, 2, H319 Do not inhale vapors. May cause dical attention in case of uncertainty. ical attention.
4.1 4.2 4.3 4.4	Proprietary 112945-52-5 7681-49-4 First Aid Measur General Information Inhalation Skin Contact Eye Contact	Blend of diurethan other methacrylate modified polyacryli Silica, amorphous Sodium fluoride	May be irritatin sensitization by Move to fresh i Take off contal Keep eyelids a Rinse mouth w give anything by Ventilate the a	BASE/LINER 53.2% 3.0% 0.90% g to eyes, respirator y skin contact. Show air. If necessary, adminated clothing. Wa part; flush with runni vith water. Do not ind by mouth to an uncoi rea. Wear eye and s	RESTORATIVE 44.6% 6.7% 0.75% y system and skin. Avoid or this safety data sheet to m ininister oxygen and/or artifish skin thoroughly with sor ng water for 15+ minutes. Cuce vomiting. Get immedia scious person. kin protection.	67/548/EEC Irritant; Xi, R 3637//38 - 43 Irritant; Xi, R 36/37/38 Harmful (Xn): R22-36/38 contact with eyes and skin. edical personnel. Get medical respiration. Seek med ap and water. Get medical attention.	Regulation (EC) No.1278/2008 (CLP) Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Skin sensitization, 1, H317 Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Acute toxicity, 4, H302 Skin irritation, 2, H315 Eye irritation, 2, H315 Eye irritation, 2, H319 Do not inhale vapors. May cause dical attention in case of uncertainty. ical attention.
4.1 4.2 4.3 4.4 4.5	Proprietary 112945-52-5 7681-49-4 First Aid Measur General Information Inhalation Skin Contact Eye Contact Ingestion Precautions for fire Information for phy Symptoms	Blend of diurethan other methacrylate modified polyacryli Silica, amorphous Sodium fluoride	May be irritatin sensitization by Move to fresh. Take off contain Keep eyelids a Rinse mouth w give anything the Ventilate the a	BASE/LINER 53.2% 3.0% 0.90% g to eyes, respirator y skin contact. Show air. If necessary, adminated clothing. We appart, flush with water. Do not ind by mouth to an uncoirea. Wear eye and siness in eyes, throat	RESTORATIVE 44.6% 6.7% 0.75% y system and skin. Avoid or this safety data sheet to mainister oxygen and/or artifish skin thoroughly with sor ng water for 15+ minutes. Cuce vomiting. Get immedianscious person. kin protection.	67/548/EEC Irritant; Xi R 3637//38 - 43 Irritant; Xi, R 36/37/38 Harmful (Xn); R22-36/38 contact with eyes and skin. edical personnel. Get medical respiration. Seek med ap and water. Get medical attention. May	Regulation (EC) No.1278/2008 (CLP) Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Skin sensitization, 1, H317 Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Acute toxicity, 4, H302 Skin irritation, 2, H315 Eye irritation, 2, H315 Eye irritation, 2, H319 Do not inhale vapors. May cause dical attention in case of uncertainty. iical attention. be irritating to mucous membranes. Never
4.1 4.2 4.3 4.4 4.5	Proprietary 112945-52-5 7681-49-4 First Aid Measur General Information Skin Contact Eye Contact Ingestion Precautions for first Information for physical services and services are services.	Blend of diurethan other methacrylate modified polyacryli Silica, amorphous Sodium fluoride	May be irritatin sensitization by Move to fresh. Take off contain Keep eyelids a Rinse mouth w give anything the Ventilate the a	BASE/LINER 53.2% 3.0% 0.90% g to eyes, respirator y skin contact. Show air. If necessary, adminated clothing. We spart; flush with runni with water. Do not individual water. Do not incorrea. Wear eye and stiness in eyes, throat ig to eyes, respirator	RESTORATIVE 44.6% 6.7% 0.75% y system and skin. Avoid or this safety data sheet to m ininister oxygen and/or artifish skin thoroughly with sor ng water for 15+ minutes. Cuce vomiting. Get immedia scious person. kin protection.	67/548/EEC Irritant; Xi R 3637//38 - 43 Irritant; Xi, R 36/37/38 Harmful (Xn); R22-36/38 contact with eyes and skin. edical personnel. Get medical respiration. Seek med ap and water. Get medical attention. May	Regulation (EC) No.1278/2008 (CLP) Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Skin sensitization, 1, H317 Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Acute toxicity, 4, H302 Skin irritation, 2, H315 Eye irritation, 2, H315 Eye irritation, 2, H319 Do not inhale vapors. May cause dical attention in case of uncertainty. iical attention. be irritating to mucous membranes. Never
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No special requirements. The usual surgical gloves worn by dental staff will limit contact with uncured material. 8.2.1.2 Hand protection 8.2.1.3 Eye protection No special requirements other than the usual safety glasses worn by dental staff.

No special requirements. Good personal hygiene, safety practices and wearing a lab coat should protect dental staff from 8.2.1.4 Skin protection unnecessary exposure to uncured material. Emergency eye wash fountain should be available. Wash hands after use 8.2.1.5 Other controls Cure material before disposing 8.2.2 Environmental exposure controls 9.0 Physical and Chemical Properties Appearance / Color Part A Part B 9.1 Yellowish Off-white 9.1.1 Physical state / Color Base / Liner Two pastes: Restorative Two thick pastes Tooth-colored Off-white 9.1.2 Faint, characteristic 9.2 Important health, safety and environmental information 9.2.1 Not determined Boiling point Not determined 9,2.2 Not determined 923 Flash point Flammability (solid, gas) Not applicable 9.2.4 9.2.5 Explosive properties Not applicable 9.2.6 Oxidizing properties Not determined 9.2.7 Vapor pressure < 1 mm Ha Part B Specific gravity 928 Part A Base / Liner 1.460 g/mL 1.380 g/mL Restorative 1.580 a/mL 1.620 g/mL 9.29 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 Stability and reactivity 10.0 10.1 Conditions to avoid Temperature > 38"C, intense light, cross-contamination Materials to avoid Reducing and oxidizing agents, peroxides, amines 10.2 Hazardous decomposition products Under fire conditions and with amounts greater than that supplied in this product, hazardous polymerization may occur with heat 10.3 build-up and release of carbon monoxide, carbon dioxide, and oxides of nitrogen. Stable material if stored and used as directed. Polymerization will occur when light-cured material is exposed to direct light. 10.4 Further information 11.0 Toxicological information Finished products in paste form present a minimal health hazard under normal conditions of use and in the quantities necessary for 11.1 Acute toxicity dental procedures Sodium fluoride: Oral rat LD50: 180 mg/kg Silica, amorphous: Oral rat LD50: 3160 mg/kg May be irritating to eyes, respiratory tract, mucous membranes or skin on contact or with prolonged exposure. 11.2 Irritation and corrosiveness 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 and/or frequent skin contact may cause allergic skin reactions in susceptible prolonged toxicity Carcinogenicity, Mutagenicity, Reproductive Toxicity individuals. Prolonged exposure to large amounts (more than in this product) may cause eye and respiratory irritation. 11.5 None known Empirical data Biocompatibility has been tested and found to be acceptable.

ACTIVA BIOACTIVE PRODUCTS are new products that have been evaluated by dentist consultants. There have been no reports of 11.6 11.7 Clinical experience 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 15.0 Regulatory Information 15.1 **EU** Regulations Class IIa medical device under MDD 93/42/EEC. Class II medical device 15.3 Health Canada Class III medical device 16.0 Other Information List of relevant R phrases 16.1 R36/37/38: Imitating 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. P261: Avoid breathing vapor. Precautionary Statements 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,
ACTIVA BioACTIVE PRODUCTS are to be sold to and used by dental professionals only.

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 Restrictions on use 16.5 Further information Corporation bears legal responsibility. The user should review any recommendations in the specific context of the intended use to determine whether they are appropriate.

National Institute for Occupational Safety (NIOSH) 16.6 Sources of key data National Institute for Occupational Safety (NOSH)
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
This Safety Data Sheet has been revised to meet the requirements of the GHS SDS format, Regulations (EC) No. 1272/2008 16.7 Information which has been added, .. (CLP) and (EC) No. 1907/2006 (REACH). Specifically, Sections 2.1, 2.2, 3.2, 16.2, 16.3 have been modified. deleted or revised

None required. Good general ventilation is sufficient to control any airborne vapors from uncured material.

PULPDENT Corporation

8.2.1.1 Respiratory protection