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

4.0	SAFETY DATA S	SHEET						
1.0		duct Name and Supr	olier					
1.1	Commercial produ		110770	CTIVE BASE / LINE	R			
1.2	Application / Use			CTIVE-RESTORATI I for use by dental p				
12.2	SIC		851 Human he		oressional only.			
.3	Use Category Manufacturer, Imp	orter	55					
1.3.1	Manufacturer		Pulpdent Corporation		SELVI SE			
	80 Oakland Street P.O. Box 780 Waterlown, MA 02472 USA							
						odent@pulpdent.com		
1.4	Authorized European Representative Advena Ltd. Pure Offices			3 (24 Hour / USA)				
1.0			Pure Offices, P					
0.0		- 74	Warwick CV34	6WE UK				
2.0	Hazards Identific Classification	cation						
2.1.1	Classification according to Regulation (EC) No 1272/2008 [CLP]							
	Hazard Class Eye irritation Hazard Category 2				Hazard Statement H319	Hazard Statement H319		
	STOT SE	3			H335			
	Skin irritation Skin sensitization	2			H315 H317			
2.1.2	Classification acc	ording to Directive 67/		it; Xi; R 36/37/38 -				
2.2	(See SECTION 16 GHS Label Eleme	6 for full text of risk phra	ases)					
	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.							
		ect from sunlight. Store			80°F.			
3.0	Composition					Danie 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 Ingredier							
	CAS Number		dient	Concentration	Concentration	Classification per	Classification per	
				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	Name of the Ingre- 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	
		Name of the Ingre-	e and es with	BASE/LINER	RESTORATIVE	67/548/EEC Irritant; Xi	Regulation (EC) No.1278/2008 (CLP) Eye irritation, 2, H319	
		Name of the Ingre- Blend of diurethan other methacrylate	e and es with c 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	Name of the Ingre- Blend of diurethan other methacrylate modified polyacryl Silica, amorphous	e and es with c 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	Name of the Ingre- Blend of diurethan other methacrylate modified polyacryl	e and es with c 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	Name of the Ingre- Blend of diurethan other methacrylate modified polyacryl Silica, amorphous	e and es with c 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	Name of the Ingre- Blend of diurethan other methacrylate modified polyacryl Silica, amorphous Sodium fluoride	e and es 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	Name of the Ingre- Blend of diurethan other methacrylate modified polyacryl Silica, amorphous Sodium fluoride	e and ss with ic acid	BASE/LINER 53.2% 3.0% 0.90% g to eyes, respirator	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	Name of the Ingre- Blend of diurethan other methacrylate modified polyacryl Silica, amorphous Sodium fluoride	e and ss with c acid May be irritatin sensitization b	BASE/LINER 53.2% 3.0% 0.90% g 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	Name of the Ingre- Blend of diurethan other methacrylate modified polyacryl Silica, amorphous Sodium fluoride	e and swith cacid May be imitatin sensitization by Move to fresh. Take off contain	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.	
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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	Name of the Ingre- Blend of diurethan other methacrylate modified polyacryl Silica, amorphous Sodium fluoride	e and ss with ic acid 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. Wa part, flush with runni ith water. Do not inco by mouth to an unco	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	Name of the Ingre- Blend of diurethan other methacrylate modified polyacryll Silica, amorphous Sodium fluoride	May be irritating sensitization by Move to fresh Take off contar Keep eyelds a Rinse mouth we 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. Wapart; flush with runni rith water. Do not inco y mouth to an unco 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 first Information for physymptoms	Name of the Ingre- Blend of diurethan other methacrylate modified polyacryll 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 clothingth runni rith water. Do not income a. 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 mediap 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 Property of the P	Name of the Ingre- Blend of diurethan other methacrylate modified polyacryll 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 runnivith water. Do not incompose the control of the co	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	
4.1 4.2 4.3 4.4 4.5 4.6 4.7	Proprietary 112945-52-5 7681-49-4 First Aid Measur General Information Skin Contact Eye Contact Ingestion Precautions for fire Information for phy Symptoms Hazards Treatment Fire Fighting Me	Name of the Ingre- Blend of diurethan other methacrylate modified polyacryll Silica, amorphous Sodium fluoride res on	May be irritatin sensitization by Move to fresh Take off contal Keep eyelids a Rinse mouth w give anything to Ventilate the a Irritation or red May be irritatin As above under the sensitive of	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 rith water. Do not incopred to eyes, respirator ar First Aid.	RESTORATIVE 44.6% 6.7% 0.75% y system and skin. Avoid or this safety data sheet to minister oxygen and/or artificials have the skin thoroughly with sor ng water for 15+ minutes. Quoe vomiting. Get immedian scious person. kin protection. or on skin. y system and skin. May cau	67/548/EEC Irritant; Xi R 3637//38 - 43 Irritant; Xi, R 36/37//38 Harmful (Xn); R22-36/38 Dentact with eyes and skin. edical personnel. Get medical respiration. Seek median and water. Get medical attention. May use sensitization by skin course.	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, H319 Do not inhale vapors. May cause dical attention in case of uncertainty. ical 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 Off-white Tooth-colored 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.

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8.2.1.1 Respiratory protection