

SAFETY DATA SHEET

SDS-0017

EndoSequence® Core Build-Up Material +

Date Issued: 02-13-2019
EDCO 19.0066 REV A

1 – IDENTIFICATION

Product Identifier	Trade Name	Product Identifier Number (REF)
	ES CBM + 50ML 1P	5027170U0
Product Use	Root canal filling material.	
Restrictions on Use	For dental use only.	
Supplier/Distributor	Brasseler U.S.A. Dental, LLC One Brasseler Boulevard Savannah, Georgia 31419, USA Tel: 1-800-841-4522	
Emergency Contact	For Chemical Emergency ONLY (spill, leak, fire, exposure, or accident) call: CHEMTREC Tel: 1-800-262-8200 (USA) +1 703-741-5500 (International)	

2 – HAZARDS IDENTIFICATION

GHS Classification and WHMIS 2015

Health Hazard	Hazard Class	Hazard Category	Signal Word	Hazard Statement	Pictogram
	Eye Irritation	2	Warning	H319 – May cause eye irritation	
	STOT SE	3	Warning	H335 – May cause respiratory irritation	
	Skin Irritation	2	Warning	H315 – May cause skin irritation	
	Skin Sensitization	1	Warning	H317 – 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	

Physical Hazard	Not applicable
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Environment Hazard	Not applicable
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3 – COMPOSITION / INFORMATION ON INGREDIENTS

CAS #	Name of the Ingredient	Concentration (wt%)	Classification According to 67/548/EEC	Classification According to Regulation (EC) No. 1278/2008 (CLP)
Proprietary	Uncured acrylate ester monomers	55-60%	Irritant; Xi, R3637/38-43	Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Skin sensitization, 1, H317
112945-52-5	Silica, amorphous	5%	Irritant; Xi, R 36/37/38	Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315

4 – FIRST AID MEASURES

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.
Inhalation	Move to fresh air. If necessary, administer oxygen and/or artificial respiration. Seek medical attention.
Skin Contact	Take off contaminated clothing. Wash skin thoroughly with soap and water.
Eye Contact	Keep eyelids apart; flush with running water for 15+ minutes. Get medical attention.
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.
Precautions for first responders	Ventilate the area. Wear eye and skin protection.
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 – FIRE-FIGHTING MEASURES

Suitable Extinguishing Media	Carbon dioxide, dry chemical, alcohol foam, or water fog. Water spray may be used to keep fire exposed containers cool.
Unsuitable Extinguishing Media	Do not use direct water stream.
Special exposure hazards in a fire	Heat may cause polymerization with rapid release of energy.
Special protective equipment for fire-fighters	Self-contained breathing apparatus

6 – ACCIDENTAL RELEASE MEASURES

Personal precautions.	Wear safety glasses, gloves and lab coat.
Environmental Precautions	Avoid releasing large amounts of uncured material into the environment. Cured / set-up material is, to our knowledge, inert.
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 – HANDLING AND STORAGE

Handling	For use only by dental professionals. Follow good hygiene practices. Avoid direct / strong light sources, temperature extremes (>27oC/80oF, <5oC/40oF), contamination, cross contamination. Recap immediately after use.
Storage	Store product tightly capped in original container at cool room temperature (<25OC). 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.
Specific uses	Dental material

8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure limit values	PEL: Not established. TLV: Not established.
Exposure controls	
Occupational exposure controls	No special equipment required under normal conditions of use
Respiratory protection	Good general ventilation is sufficient to control any airborne vapors.
Hand protection	No special requirements other than the usual surgical gloves worn by dental staff.
Eye protection	No special requirements other than the usual safety glasses worn by dental staff.
Skin protection	Good personal hygiene and safety practices; wearing a lab coat.
Other controls	Emergency eye wash fountain should be available. Wash hands after use.
Environmental exposure controls	Cure material before disposing.

9 – PHYSICAL AND CHEMICAL PROPERTIES

Characteristics			
Appearance /Color / Physical state	Part A: Thick yellow paste Part B: Thick white paste	Explosive properties	Not applicable
Odor	Faint, characteristic	Oxidizing properties	Not determined
pH	Not determined	Vapor pressure	< 1 mm Hg
Boiling Point	Not determined	Specific gravity	1.006
Flash Point	Not determined	Solubility in water	Nil
Flammability (solid, gas)	Not applicable	Partition coefficient	Not determined
Viscosity	Not determined	Vapor density	Not determined
Evaporation Rate	Not Determined		

10 – STABILITY AND REACTIVITY

Conditions to avoid	Temperature > 38C, intense light, cross-contamination.
Materials to avoid	Reducing and oxidizing agents, peroxides, amines.
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.
Conditions To Avoid	Avoid unintentional contact with water to prevent premature setting/curing; contact will result in hydration of the product and produces (caustic) calcium hydroxide.
Further information	Stable material if stored and used as directed. Polymerization will occur when light-cured material is exposed to direct light.

11 – TOXICOLOGICAL INFORMATION

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 LD50: 180 mg/kg Silica, amorphous: Oral rat LD50: 3160 mg/kg
Irritation and corrosiveness	May be irritating to eyes, respiratory tract, mucous membranes or skin on contact or with prolonged exposure.
Sensitization	May be sensitizing. Prolonged or frequent skin contact may cause allergic skin reactions in some susceptible individuals.
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.
Carcinogenicity, Mutagenicity, Reproductive Toxicity	None known
Empirical data	Biocompatibility has been tested and found to be acceptable.
Clinical experience	ES CBM+ has been on the market (under a different brand name) for almost size year with no reports of adverse events or serious complaints.

12 – ECOLOGICAL INFORMATION

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.
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13 – DISPOSAL CONSIDERATIONS

Regulations	Follow all local and national government regulations in disposing material or contaminated packaging.
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14 – TRANSPORT INFORMATION

Restrictions	None. Not regulated.
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15 – REGULATORY INFORMATION

EU Regulations	Class IIa medical device under MDD 93/42/EEC.
US FDA	Class II Medical Device

16 – OTHER INFORMATION

List of relevant R phrases	R36/37/38: Irritating to eyes, respiratory system and skin. R43: Sensitizing by skin contact.
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.
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 □ 27oC / 80oF.
Restrictions on use	EndoSequence BC Liner is to be sold to and used by dental professionals only.
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.
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
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.