HENRY SCHEIN®
DENTAL

GENERAL BUSINESS: 0800 808 855
FAX: 0508 808 555
www.henryschein.co.nz

Material Safety Data Sheet Cover-Sheet – This page provides additional New Zealand specific information for this product and must be read in conjunction with the Safety Data Sheet (SDS) attached

Product Name:	Edge BioCeramic Retrofill
Manufacturer:	Innovative BioCeramix Inc.
SDS Expiry:	15 August 2028
Supplier Details:	Henry Schein New Zealand 243-249 Bush Road, Rosedale, Auckland, 0632 PO Box 101 140, North Shore, Auckland 0745 Ph. 0800 808 855 www.henryschein.co.nz
Emergency Contacts:	Poisons/Hazardous Chemical Info Centre – 0800POISON/0800764766 (24 Hours) Phone 111 for Fire, Ambulance or Police
HSNO Class/Category:	6
HSNO Group Standard:	Dental Products Subsidiary Hazard Group Standard 2020 HSR002558
Statements/Pictograms:	As per attached Safety Data Sheet (SDS)
Date Prepared:	This coversheet was prepared – August 2024

This SDS coversheet has been produced by Henry Schein NZ and has been prepared in accordance with NZ EPA advice on making overseas SDS compliant to HSNO Act. The above information is based on the present state of our knowledge of the product at the time of publication. It is given in good faith, no warranty is implied with respect to the quality or the specifications of the product. Users must satisfy that the product is entirely suitable for their purpose. The SDS and this coversheet may be revised from time to time, please ensure you have a current copy.

1 – IDENTIFICATION

Product Identifier	Trade Name	Product Identifier Number (REF)
	EDGEBIOCERAMIC RETROFILL™ AND PERFORATION REPAIR MATERIAL 0.5G	USEBIORMEU

Product Use	Root canal repair and filling material.
Restrictions on Use	For dental use only.
Supplier	Innovative BioCeramix Inc. 101 - 8218 North Fraser Way Burnaby, BC V3N 0E9 Canada Tel: +1 604-221-6800
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
	Skin irritation	2	Warning	H315 Causes skin irritation	
	Eye irritation	2A	Warning	H319 Causes serious eye irritation	

Precautionary Statements		
	P264	Wash hands thoroughly after handling.
	P280	Wear protective gloves, protective clothing, eye protection and face protection.
	P302 + P352	IF ON SKIN: Wash with plenty of soap and water.
	P321	Specific treatment: Wash skin thoroughly with cool water and pH-neutral soap or a mild detergent intended for use on skin.
	P332 + P313	If skin irritation occurs: Get medical advice / attention.
	P337 + P313	If eye irritation persists: Get medical advice / attention.
	P362 + P364	Take off contaminated clothing and wash it before reuse.
	P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Physical Hazard	This product reacts chemically with water or moisture, and specific intermediate products of this reaction (i.e. calcium hydroxide, is present only while the product is setting or curing) can produce a strong alkaline material than that of the dry paste.

Environment Hazard	Not applicable

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3 – COMPOSITION / INFORMATION ON INGREDIENTS

CAS #	EC Number	Index No.	REACH Registration No.	Concentration (wt%)	Chemical Name	Classification According to 67/548/EEC	Classification According to Regulation (EC) No. 1272/2008 (CLP)
12168-85-3	Not applicable	Not applicable	Not applicable	30.0 – 36.0%	Tricalcium silicate	Irritant: Xi; R36 R38	Skin Irrit. 2 H315 Eye Irrit. 2 H319
1314-23-4	215-227-2	Not applicable	Not applicable	15.0 – 18.0%	Zirconium oxide		
1314-61-0	215-238-2	Not applicable	Not applicable	12.0 – 15.0%	Tantalum pentoxide		
10034-77-2	Not applicable	Not applicable	Not applicable	9.0 – 13.0%	Dicalcium silicate		
10034-76-1	231-900-3	Not applicable	Not applicable	3.0 – 8.0%	Calcium sulfate		
Not applicable	Additives: Fillers: • None are classified as hazardous to the health or environment and do not contribute to the classification of the product. • The specific chemical identity and the exact concentration of the fillers in the product have been withheld as per Confidential Business Information (CBI).				Not applicable	Not applicable	Proprietary

4 – FIRST AID MEASURES

Route of Exposure	Most Important Symptoms/Effects, Acute and Delayed	First Aid Treatment
Skin Contact	• Skin irritation, drying, cracking or fissuring of the skin. • Prolonged exposure can cause severe skin damage in the form of chemical (caustic) burns.	• Wash skin thoroughly with cool water and pH-neutral soap or a mild detergent intended for use on skin. • Wear gloves to remove any contaminated clothes and shoes from the individual. • Get medical attention in all cases of prolonged exposure to the product, freshly cured product or prolonged wet skin exposure to the product.
Eye Contact	• Severe irritation and/or inflammation. • Blindness in severe cases.	• Immediately rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. • Continue rinsing, include under lids to remove all particles. • Get immediate medical attention.
Inhalation	• Irritation to the moist mucus membranes of the nose, throat and upper respiratory system. • Pre-existing upper respiratory and lung diseases may be aggravated.	• Move exposed individual from the area into fresh air. • Get medical attention if coughing and other symptoms do not subside.
Ingestion	• Internal discomfort or irritation to the digestive tract.	• Do NOT induce vomiting. • If individual is conscious, use water to rinse out the mouth and have the individual drink plenty of water. • If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain an open airway and prevent aspiration. Observe the individual carefully. • Never give anything by mouth to an unconscious individual (i.e. showing signs of being sleepy or with reduced awareness). • Get immediate medical attention.

5 – FIRE-FIGHTING MEASURES

Conditions of Flammability	Not flammable or combustible.
Suitable Extinguishing Media	Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Unsuitable Extinguishing Media	There is no restriction on the type of extinguisher.
Specific Hazards Arising From the Product	None known.
Special Protective Actions Equipment and Precautions for Fire-Fighters	• Wear self-contained breathing apparatus and protective gloves for firefighting. • Equipment should be thoroughly decontaminated after use. • Prevent spillage from entering drains or water courses.

6 – ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures	• Wear appropriate personal protective equipment to prevent contamination of skin, eyes and personal clothing (see Section 8). • Avoid contact with the product: o Avoid contact to the product, freshly cured product or prolonged wet skin exposure to the product. o Avoid actions that cause dried product to become airborne. o Avoid inhalation of dried product dust. • Use a scoop or moist paper towel(s) to clean up spilled product.
Environmental Precautions	• Prevent further spillage. • Keep product away from drains, surface and ground water.
Methods and Materials for Containment and Cleaning Up	• Use a scoop or moist paper towel(s) to clean up spilled product. Dispose of in a suitable sealed container. • Dispose of waste product according to local state and federal regulations. • Cover drains. • Wash spilled area with large amounts of water and dry thoroughly.

7 – HANDLING AND STORAGE

Precautions for Safe Handling	• Avoid contact with skin and eyes. • Avoid inhalation of dried product. • Wear personal protective equipment. • Remove contaminated clothing and personal protective equipment before entering eating areas. • Wash hands after handling product. • Remove contaminated clothing and personal protective equipment. Wash before reuse. • Avoid contact with ammonia, ammonia nitrate, chlorine or chlorine containing items.
Conditions for Safe Storage	• Air and moisture sensitive. • Store at room temperature in a dry area. • Store tightly closed in the original packaging. Keep dry until used. • Protect from excessive heat and cold. • Protect packaging against physical damage. • Store away from incompatible materials, and from foodstuffs and beverages. • Do not store near ammonia, ammonia nitrate, chlorine or chlorine containing items.

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8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters	The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.	
Appropriate Engineering Controls	Use and store in a well-ventilated area.	
Individual Protections Measures, Such as Personal Protective Equipment (PPE)	**Eye / Face Protection** 	• Safety glasses with side shields. • Tightly sealed safety goggles. • Face shields. • Contact lenses should not be worn.
	Skin Protection  	• Glove material has to be impermeable and resistant to the product: o Exam gloves: nitrile rubber or latex. o Recommended thickness of the glove material: ≥0.38mm • Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. • Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practice. • Wash and dry hands after handling product. • Lightweight impermeable protective work clothing (lab coat), as appropriate, to prevent skin contact. • Remove contaminated clothing and personal protective equipment before entering eating areas. • Remove contaminated clothing and personal protective equipment. Wash before reuse.
	Respiratory Protection 	• Surgical face mask • Handle product in a well-ventilated area.
	Thermal Hazards	Not applicable
	Hygiene Measures	• Handle in accordance with good industrial hygiene and safety practice. • Keep away from foodstuffs and beverages. • Wash hands before breaks and at the end of work.

9 – PHYSICAL AND CHEMICAL PROPERTIES

Appearance	**State**	Solid (thick paste / putty)	**Upper / Lower Flammability or Explosive Limits**	Not available
	Colour	White		
Odour	No distinct odour		**Vapour Pressure**	Not available
Odour Threshold	Not available		**Vapour Density**	Not available
pH	>12 (Basic)		**Relative Density**	Not available
Melting Point / Freezing Point	Not available		**Solubility (with water)**	Slightly soluble
Initial Boiling Point and Boiling Range	Not available		**Partition Coefficient: n-octanol / water**	Not available
Flash Point	Not available		**Auto-ignition Temperature**	Not available
Evaporation Rate	Not available		**Decomposition Temperature**	Not available
Flammability	Not available		**Viscosity**	Not available

10 – STABILITY AND REACTIVITY

Reactivity	Contact with water will result in hydration of the product and produces (caustic) calcium hydroxide.
Chemical Stability	• Stable under recommended storage conditions. • Keep dry.
Possibility of Hazardous Reactions	Not available
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.
Incompatible Materials	Incompatible with acids, ammonia, ammonia nitrate, ammonium salts, aluminum metal and chlorine.
Hazardous Decomposition Products	• Decomposition will not spontaneously occur. • Contact with water will result in hydration of the product and produces (caustic) calcium hydroxide.

11 – TOXICOLOGICAL INFORMATION

Emergency Overview	This product is a white paste that poses little immediate hazard. A single-term exposure to the paste is not likely to cause serious harm. However, exposure of sufficient amount and duration (either single or multiple) to the moist product can cause serious irritation to the skin and eyes in the form of chemical (caustic) burns. Similar tissue damage can occur if wet or moist areas of the body are exposed for sufficient duration to the product.

Numerical Measures of Toxicity				
Chemical Name	**CAS #**	**ACGIH**	**OSHA PEL**	**LD_{50}**
Tricalcium silicate	12168-85-3	10 mg/m^3 total dust	5 mg/m^3 respiratory dust 10 mg/m^3 total dust	Not available
Dicalcium silicate	10034-77-2			
Zirconium oxide	1314-23-4	5 mg/m^3 total dust	5 mg/m^3 TWA	Not available
Tantalum pentoxide	1314-61-0	5 mg/m^3 total dust	5 mg/m^3 total dust	Oral: >4000 mg/kg Rat: 8000 mg/kg
Calcium sulfate	10034-76-1	10 mg/m^3 (TWA) inhalable fraction	15 mg/m^3 total dust 5 mg/m^3 respiratory fraction	No LD50 / LC50

Routes of Exposure	**Symptoms Related to Physical, Chemical and Toxicological Characteristics**	**Delayed and Immediate Effects Chronic Effects from Short and Long-Term Exposure**	**Target Organ(s)**
Skin Contact	Skin irritation, drying, cracking or fissuring of the skin.	Severe skin damage in the form of chemical (caustic) burns.	Skin
Eye Contact	Severe irritation and/or inflammation.	Blindness in severe cases.	Eye
Inhalation	Irritation to the moist mucus membranes of the nose, throat and upper respiratory system.	Pre-existing upper respiratory and lung diseases may be aggravated.	Mucous membranes of nose, throat and upper respiratory system.
Ingestion	Internal discomfort or irritation to the digestive tract.	Ill effects are possible if large quantities are consumed.	Digestive system

Acute Toxicity	Product is not classified as a toxic substance.
Skin Corrosion / Irritation	May cause skin irritation.
Serious Eye Damage / Irritation	May cause serious eye irritation.
Respiratory or Skin Sensitization	No allergic potential after multiple uses and good tolerance by subcutaneous tissues.
Germ Cell Mutagenicity	No mutagenic effect.
Carcinogenicity (NTP, IARC, OSHA)	Ingredients not listed as carcinogens.
Reproductive Toxicity	Not available
Specific Target Organ Toxicity (STOT) – Single Exposure	Product is not classified as a toxic substance.
Specific Target Organ Toxicity (STOT) – Repeated Exposure	Product is not classified as a toxic substance.
Aspiration Hazard	Not available
Interactive Effects	Not available
Other Information	Not applicable

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12 – ECOLOGICAL INFORMATION

Toxicity	Not available	**Mobility in Soil**	Not available
Persistence and Degradability	Not available	**Other Adverse Effects**	No known significant effects or critical hazards.
Bioaccumulative Potential	Not available		

13 – DISPOSAL CONSIDERATIONS

Disposal Methods	• For the safe handling of disposing of this product, wear appropriate personal protective equipment to prevent contamination of skin, eyes and personal clothing (see Section 8). • Dispose of waste product or contaminated product in a suitable sealed container. • Dispose of product according to local state and federal regulations.
Physical / Chemical Properties Affecting Disposal Options	No known precautions.
Discourage Sewage Disposal	Do not dispose of product down drains or from entering sewage systems.
Special Precautions for Incineration or Landfill	No known precautions.

14 – TRANSPORT INFORMATION

UN Number	Not applicable, the product is not classified as Dangerous Goods.
UN Proper Shipping Name	Not applicable, the product is not classified as Dangerous Goods.
Transport Hazard Class(es)	Not classified as a transport hazard in accordance with the UN Model Regulations.
Packing Group	Not applicable, the product is not classified as Dangerous Goods.
Environmental Hazards	• Product is not known as a marine pollutant according to the IMDG Code. • Product is not an environmental hazard according to the UN Model Regulations, ADR, RID and ADN.
Precautions for User	Not applicable
Transport in Bulk (According to Annex II of MARPOL 73/78[9] and the IBC Code)	Not applicable

15 – REGULATORY INFORMATION

Status under REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006;

- This device is classified as an irritant:
  - Skin irritation (Category 2)
  - Eye irritation (Category 2)

Status under USDOL-OSHA Hazard Communication Rule, 29 CFR 1910,1200:

- The ingredients in this product (calcium silicate compounds, tantalum pentoxide, zirconium oxide and calcium sulfate) are considered to be "hazardous chemicals" under this regulation.

16 – OTHER INFORMATION

Date of Preparation	2023-08-15

This product should be used according to manufacturer's directions. Safety precautions presented above may not be adequate for all individuals or situations. Inexperienced product users should obtain proper training before using or handling this product. Users have the responsibility to comply with all laws and procedures applicable to the products' safe handling and use, determine the suitability of the product for its intended use, and understand possible hazards associated with mixing this product with other materials. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. The supplier and/or manufacturer of this product shall not be held liable for damage resulting from handling, misuse or from contact with this product.