

SAFETY DATA SHEET

SDS 4608

Date Issued:2023.09.20
Rev B/3

Injectable Root Canal Bioceramic Sealer

1-IDENTIFICATION

Product Identifier	Trade Name	Product Identifier Number (REF)
	Injectable Root Canal Bioceramic Sealer	0.5g , 1g, 2g
Product Use	Injectable Root Canal Bioceramic Sealer	
Restrictions on Use	For dental use only.	
Supplier	Beijing C- Root Dental Medical Devices Co., LTD. Room 301, Building 10, Yard 12, Middle Juyuan Road, Mapo Town, Shunyi District, Beijing, China	
	Tel: +86 10 56467681	
Emergency Contact	Tel: +86 18601290788	

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 .
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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. 1278/2008 (CLP)
1314-23-4	215-227-2	Not applicable	Not applicable	10-30	Zirconium oxide	Irritant:Xi; R36 R38	Skin Irrit.2 H315 Eye Irrit. 2 H319
7758-23-8	231-837-1	Not applicable	Not applicable	2-10	Calcium phosphates		
Not applicable	Not applicable	Not applicable	Not applicable	20-40	Strontium Silicates		
1305-62-0	215-137-3	Not applicable	Not applicable	1-5	Calcium Hydroxide		
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	0.1-4.0%

4-FIRST AID MEASURES

Route of Exposure	Most Important Symptoms/Effects, Acute and Delayed	First Aid Treatment
Skin Contact	<ul style="list-style-type: none"> Skin irritation,drying,cracking or fissuring of the skin. Prolonged exposure can cause severe skin damage in the form of chemical (caustic) burns. 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Severe irritation and/or inflammation. Blindness in severe cases 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Irritation to the moist mucus membranes of the nose,throat and upper respiratory system. Pre-existing upper respiratory and lung diseases may be aggravated. 	<ul style="list-style-type: none"> Move exposed individual from the area into fresh air. Get medical attention if coughing and other symptoms do not subside.
Ingestion	<ul style="list-style-type: none"> Internal discomfort or irritation to the digestive tract. 	<ul style="list-style-type: none"> 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.

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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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Wear appropriate personal protective equipment to prevent contamination of skin, eyes and personal clothing(see Section 8). Avoid contact with the product: <ul style="list-style-type: none"> Avoid contact to the product, freshly cured product or prolonged wet skin exposure to the product. Avoid actions that cause dried product to become airborne. Avoid inhalation of dried product dust. Use a scoop or moist paper towel(s) to clean up spilled product.
Environmental Precautions	<ul style="list-style-type: none"> Prevent further spillage. Keep product away from drains,surface and ground water.
Methods and Materials for Containment and Cleaning Up	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Safety glasses with side shields. Tightly sealed safety goggles. Face shields Contact lenses should not be worn.
	Skin Protection 	<ul style="list-style-type: none"> Glove material has to be impermeable and resistant to the product: <ul style="list-style-type: none"> Exam gloves: nitrile rubber or latex. 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.
		<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Surgical face mask Handle product in a well-ventilated area.
Thermal Hazards	Not applicable	
Hygiene Measures	<ul style="list-style-type: none"> 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 (paste)	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

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10-STABILITY AND REACTIVITY

Reactivity	Contact with water will result in hydration of the product and produces (caustic) calcium hydroxide.
Chemical Stability	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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.
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Numerical Measures of Toxicity

Chemical Name	CAS#	ACGIH	OSHA PEL	LD ₅₀
Zirconium oxide	1314-23-4	5mg/m ³ total dust	5mg/m ³ TWA	Not available
Calcium phosphate	7758-23-8	10mg/m ³ total dust	5mg/m ³ respiratory dust 10mg/m ³ total dust	2000mg/kg
Strontium silicate	Not applicable	Not available	Not available	Not available
Calcium hydroxide	1305-62-0	5mg/m ³	5mg/m ³ TWA (respirable fraction) 15mg/m ³ TWA (total dust)	7300mg/kg

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 available

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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	<ul style="list-style-type: none"> 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 know 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)	The goods can be shipped by air in accordance with International Civil Aviation Organization (ICAO) , TI or International Civil Aviation Association (IATA), DGR Packing Instructions (PI) P1967 Section II appropriate of IATA DGR 64rd (2023 Edition) for transportation.
Packing Group	Not applicable, the product is not classified as Dangerous Goods.
Environmental Hazards	<ul style="list-style-type: none"> 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 73/78⁹ 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;	<ul style="list-style-type: none"> This device is classified as an irritant: <ul style="list-style-type: none"> Skin irritation (Category 2) Eye irritation(Category 2)
Status under USDOL-OSHA Hazard Communication Rule,29 CFR 1910.1200:	<ul style="list-style-type: none"> The ingredients in this product (zirconium oxide, calcium hydroxide are considered to be "hazardous chemicals" under this regulation.

16-OTHER INFORMATION

Date of Preparation	2021.12.06
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.	

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