DENTSPLY Tulsa Dental Specialties

Safety Data Sheet

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1. PRODUCT IDENTIFICATION

Trade Name (as labeled):	**ProRoot® MTA Root Canal Repair Material**
Chemical Name/Classification:	**ProRoot® MTA Root Canal Repair Material**
Product Identifier (Part/Item Number):	**(PRCEM-**PROROOT GRAY MTA**), (PRCEMW-**PROROOT CEM WHITE MTA**), (PRCEMWSP-**ROROOT MTA White**), (PROROOTCM2W-**PROROOT MTA White**), (PROROOTMTAW-**PROROOT WHITE MTA**), (PRMANSYSW-**PROROOT WHITE MTA**), (PROROOT2W-**PROROOT MTA White**), (PROROOT5W-**PROROOT MTA White**)**
U.N. Number:	**n/a**
U.N. Dangerous Goods Classification:	**n/a**
Recommended Use:	**Dental use only**
Restrictions on Use:	**N/A**
Manufacturer/Supplier Name:	**DENTSPLY Tulsa Dental Specialties**
Manufacturer/Supplier Address:	**608 Rolling Hills Dr., Johnson City, TN 37604**
Manufacturer/Supplier Telephone Number:	**1-800-924-7393 (Product Information)**
Emergency Contact Telephone Number:	**1-800-262-8200**
Email address:	**chemtrec@chemtrec.com**

2. HAZARD(s) IDENTIFICATION

Hazard/Danger Classification:

Health	Environmental	Physical
Danger – Causes serious eye damage, skin irritation, allergic skin reaction & respiratory irritation.	N/A	Since this product is used in small qty. (<1gram) there is little chance for exposure. When cement reacts with water a strong alkaline solution is produced.

Associated Hazards:

Hazard Statements	Precautionary Statements
N/A	Wash thoroughly after handling. Do not breathe dust. Do not get into eyes.

EU Classification: n/a

EU Risk (R) and Safety (S) Phrases: n/a

HAZARDOUS SUBSTANCE. NON-DANGEROUS GOODS. According to NOHSC Criteria, and ADG Code.

Refer to Section 16 for the full text of the EU Classifications and R Phrases.

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Components	C.A.S. # EC#	IUPAC Name	Substance Classification	WT %
Portland cement	65997-15-1	n/a	n/a	60 - 90%
Bismuth oxide	1304-76-3	Bismuth Trioxide	n/a	10 - 40%

Refer to Section 16 for the full text of the GHS and H phrases and EU Classifications and R Phrases.

4. FIRST-AID MEASURES

Routes of Exposure	First Aid Instructions
Eye	Immediately flush eyes thoroughly with water. Continue flushing eye for at least 15 minutes, including under lids, to remove all particles. Call physician immediately.
Skin	Wash skin with cool water and pH-neutral soap or a mild detergent intended for use on skin. Seek medical treatment in all cases of prolonged exposure to wet material, freshly cured product, or prolonged wet skin exposure to the dry powder.
Inhalation	Remove to fresh air. Seek medical help if coughing and other symptoms do not subside. ("Inhalation" of gross amounts of ProRoot MTA Root Canal Repair Material requires immediate medical attention.)
Ingestion	Do not induce vomiting. If conscious, have the victim drink plenty of water and call a physician immediately.
Most important symptoms of exposure	SWALLOWED: For advice, contact a Poisons Information Centre or a doctor at once. · Urgent hospital treatment is likely to be needed. If swallowed do NOT induce vomiting. If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. Observe the patient carefully. Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious. Give water to rinse out mouth,

	then provide liquid slowly and as much as casualty can comfortably drink. Transport to hospital or doctor without delay.
Other	n/a
Note to Physicians (Treatment, Testing, and Monitoring) n/a	

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media:	There is no restriction on the type of extinguisher which may be used. Use extinguishing media suitable for surrounding area.
Fire Fighting Procedures:	Wear breathing apparatus plus protective gloves for fire only. Prevent, by any means available, spillage from entering drains or water courses. Use firefighting procedures suitable for surrounding area. Equipment should be thoroughly decontaminated after use.
Specific Hazards Arising from the Chemical:	None. (Although product poses no fire-related hazards, a self-contained breathing apparatus is recommended to limit exposures to combustion products when fighting any fire.)
Precautions for Fire Fighters:	Decomposition may produce toxic fumes of: silicon dioxide (SiO2), metal oxides. May emit poisonous fumes. May emit corrosive fumes. FIRE INCOMPATIBILITY None known. HAZCHEM-None

Recommended Protective Equipment for Fire Fighters:			
EYES/FACE	SKIN	RESPIRATORY	THERMAL

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, PPE and Emergency Procedures: Collect dry material using a scoop. Avoid actions that cause dust to become airborne. Avoid inhalation of dust and contact with skin. Wear appropriate personal protective equipment as described in Section 8.
Environmental Precautions: Scrape up wet material and place in an appropriate container. Allow the material to "dry" before disposal. Do not attempt to wash ProRoot MTA Root Canal Repair Material down drains.
Methods and Materials for Containment and Clean-up: Dispose of waste material according to local, state and federal regulations. IF DRY: Use dry clean up procedures and avoid generating dust. Collect residues and place in sealed plastic bags or other containers for disposal. IF WET: Vacuum/shovel up and place in labeled containers for disposal. ALWAYS: Wash area down with large amounts of water and prevent runoff into drains. If contamination of drains or waterways occurs, advise Emergency Services. **Personal Protective Equipment advice is contained in Section 8 of the SDS**

Recommended Personal Protective Equipment for Containment and Clean-up:			
EYES/FACE	**SKIN**	**RESPIRATORY**	**Skin**

7. HANDLING AND STORAGE

Precautions for Safe Handing: Avoid all personal contact, including inhalation. Wear protective clothing when risk of exposure occurs. Use in a well-ventilated area. Promptly remove dusty or wet clothing. Launder before reuse. Use local exhaust ventilation to minimize airborne dusts. Avoid contact with ammonia, ammonia nitrate and chlorine or chlorine containing items.

Conditions for Safe Storage: Store in original containers. Keep containers securely sealed. Store in a cool, dry area protected from environmental extremes. Store away from incompatible materials and foodstuff containers. Protect packaging against physical damage. Do not store near ammonia, ammonia nitrate and chlorine or chlorine containing items.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits: Avoid actions that cause dust to become airborne. Use local or general ventilation to control exposures below applicable exposure limits.

Biological Exposure Limits: Dispose of waste material according to local, state and federal regulations.

Appropriate Engineering Controls: Well ventilation

Individual Protection Measures (PPE)
Specific Eye/face Protection: Wear goggles, safety glasses, or a face shield.
Specific Skin Protection: Wear latex or nitrile gloves. Wear impervious protective clothing, including lab coat, apron or coveralls, as appropriate to prevent skin contact.
Specific Respiratory Protection: Handle the product in a well-ventilated area.
Specific Thermal Hazards: n/a

Recommended Personal Protective Equipment			
EYES/FACE	SKIN	RESPIRATORY	Skin

Environmental Exposure Controls: DO NOT discharge into sewer or waterways.
General Hygiene Considerations and Work Practices: n/a
Protective Measures During Repair and Maintenance of Contaminated Equipment: n/a

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Grey or White powder	**Explosive limits:**	n/a
Odor:	No distinct odor	**Vapor pressure:**	n/a
Odor threshold:	n/a	**Vapor density:**	n/a
pH:	12 to 13	**Relative density:**	4 to 4.5
Melting/freezing point:	n/a	**Solubility:**	n/a
Initial boiling point and range:	n/a	**Partition coefficient: n-octanol/water:**	Slightly soluble
Flash point:	n/a	**Auto-ignition temperature:**	n/a
Evaporation rate:	n/a	**Decomposition temperature:**	n/a
Flammability:	n/a	**Viscosity:**	n/a
Explosive Properties:	n/a	**Oxidizing Properties:**	n/a

10. STABILITY AND REACTIVITY

Reactivity: Wet product is alkaline (caustic/basic). It is incompatible with acids, ammonia, ammonia nitrate, ammonium salts, aluminum metal and chlorine.
Chemical Stability: Stable
Possibility of Hazardous Reactions: may not occur
Conditions to Avoid: Avoid unintentional contact with water to prevent premature setting/curing.
Incompatible materials: Wet ProRoot MTA Root Canal Repair Material is alkaline (caustic/basic). It is incompatible with acids, ammonia, ammonia nitrate, ammonium salts, aluminum metal and chlorine.

Hazardous Decomposition Products: Decomposition will not spontaneously occur. Addition of water to the powder results in hydration and produces (caustic) calcium hydroxide.

11. TOXICOLOGICAL INFORMATION

Toxicity, Environmental Fate, Physical/Chemical Data, or Other Data Supporting Environmental Hazard Statements: No recognized unusual toxicity to plants or animals.

Emergency Overview:

ProRoot® MTA Root Canal Repair Material is a powder that poses little immediate hazard. A single short-term exposure to the dry powder is not likely to cause serious harm. However, exposure of sufficient amount and duration (either single or multiple) to moist product can cause serious, potentially irreversible tissue (skin or eye) destruction in the form of chemical (caustic) burns, including third-degree burns. The same type of tissue destruction can occur if wet or moist areas of the body are exposed for sufficient duration to the dry product.

Routes of Exposure	Signs and Symptoms	Single, Repeated, or Lifetime Exposure	Severity (Mild, Moderate, Severe)	Acute and Chronic Health Effect(s)	Target Organ(s)	LD50 Testing Data (as applicable)	LC50 Testing Data (as applicable)
Eye:	Irritation or inflammation	**Single**	**Moderate**	Blindness in severe cases	eye	N/A	**N/A**
Skin:	Skin dryness, mild irritation	**Single**	**Mild**	Severe skin damage in the form of (caustic) chemical burns.	skin	N/A	**N/A**
Inhalation:	Irritation to moist mucous membranes of the nose, throat and upper respiratory system.	**Repeated**	**Mild**	Lung injury (silicosis) can occur.	Mucous membranes of nose, throat and upper respiratory system.	N/A	**N/A**
Ingestion:	Small quantities are not known to be harmful.	**Single**	**Mild**	Ill effects are possible if large quantities are consumed.	Digestive system	N/A	**N/A**
Other:	n/a	n/a	n/a	n/a	n/a	n/a	n/a

Medical Conditions Aggravated by Exposure: Pre-existing upper respiratory and lung diseases.

Carcinogenicity: Ingredients not listed as carcinogens.

12. ECOLOGICAL INFORMATION

Toxicity: No recognized unusual toxicity to plants or animals.

Persistence and Degradability: n/a
Bio-accumulative Potential: n/a
Mobility in Soil: n/a
Other Adverse Effects: n/a
Results of PBT/vPvB Assessment: n/a

13. DISPOSAL CONSIDERATIONS

Regulations: Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked. Dispose of waste material according to local, state and federal regulations.
Properties (Physical/Chemical) Affecting Disposal: n/a
Waste Treatment Recommendations: DO NOT allow wash water from cleaning or process equipment to enter drains. It may be necessary to collect all wash water for treatment before disposal. Consult State Land Waste Management Authority for disposal.

14. TRANSPORT INFORMATION

UN Identification Number: n/a
UN Proper Shipping Name: ProRoot® MTA Root Canal Repair Material
Transport hazard class(es): HAZCHEM: None (ADG7) NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS: UN, IATA, IMDG
Packing Group: n/a
Special precautions for user: n/a

15. REGULATORY INFORMATION

U.S. Federal Regulations

Status under USDOL-OSHA Hazard Communication Rule, 29 CFR 1910,1200: Status under USDOL-OSHA Hazard Communication Rule, 29 CFR 1910, 1200- The major components of ProRoot® MTA Root Canal Repair Material (calcium silicate compounds and calcium compounds containing iron and aluminum and gypsum) are considered to be “hazardous chemicals” under this regulation; thus, the product should be part of hazard communication program(s).

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): Not listed

Toxic Substances Control Act (TSCA): Some substances in the major component of ProRoot MTA Root Canal

Repair Material are on the TSCA inventory list.

Clean Water Act (CWA): n/a

Clean Air Act (CAA): n/a

Status under CERCLA /Superfund, 40 CFR 117 and 302: Not listed.

Hazard Category under SARA (Title III), Section 311 and 312: The major components of ProRoot MTA Root Canal Repair Material (calcium silicate compounds and calcium compounds containing aluminum oxide and gypsum) qualify as "hazardous substances" with delayed health effects.

Status under SARA (Title III), Section 313: Not subject to reporting requirements under Section 313.

Immediate Hazard:	n/a	**Pressure Hazard:**	n/a
Delayed Hazard:	n/a	**Reactivity Hazard:**	n/a
Fire Hazard:	n/a		

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372): Not subject to reporting requirements under Section 313.

Components	C.A.S. #	WT %
n/a	n/a	n/a

State Regulations

California: This product contains the following chemicals(s) known to the State of California to cause cancer, birth defects or reproductive harm: This product contains chemicals (trace metals) known to the State of California to cause cancer, birth defects or other reproductive harm. California law requires the manufacturer to give the above warning in the absence of definitive testing to prove that the defined risks do not exist.

Components	C.A.S. #	WT %
Portland cement	65997-15-1	60 - 90%

International Regulations

Canadian Environmental Protection Act: Not listed.

Canadian Workplace Hazardous Materials Information System (WHMIS): The major component of ProRoot MTA Root Canal Repair Material is considered to be a hazardous material under the Hazardous Products Act as defined by the Controlled Products Regulations (Class E-Corrosive Material) and is therefore subject to the labeling and MSDS requirements of the Workplace Hazardous

Materials Information System (WHMIS). The major component of ProRoot MTA Root Canal Repair Material is considered to be a hazardous material under the Hazardous Products Act as defined by the Controlled Products Regulations (Class E - Corrosive Material). Therefore, the product is subject to the labeling and MSDS requirements of the Workplace Hazardous Materials Information System (WHMIS).

European Inventory of Existing Chemicals (EINECS): n/a

16. OTHER INFORMATION

Full text of Classification abbreviations used in Section 2 and 3: N/A

OTHER IMPORTANT INFORMATION: This product should be used according to manufacturer's directions. A key to using the product safely requires the user to recognize that ProRoot MTA Root Canal Repair Material chemically reacts with water, and that some of the intermediate products of this reaction (that is, those present only while the product is setting or curing) pose a far more severe hazard than does the material itself.

While the information provided in this safety data sheet is believed to provide a useful summary of the hazards of the product as it is commonly used, the sheet cannot anticipate and provide all of the information that might be needed in every situation. Inexperienced product users should obtain proper training before using this product.

EC safety and risk phases

S13, S22, S24, S25, S26, S28, S35, S62

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