MATERIAL SAFETY DATA SHEET (MSDS)
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ProRoot® MTA (Mineral Trioxide Aggregate) Root Canal Repair Material

Product Code/Part Number
PRMANSYSW
PRCEMW

Manufactured in the U.S.A. by
DENTSPLY Tulsa Dental
5100 East Skelly Dr, Suite 300
Tulsa, OK 74135-6546
1.800.662.1202
Fax: 1.800.597.2779
www.tulsadental.dentsply.com

European Mandatory
DENTSPLY DeTrey GmbH
De-Trey-Straße 1
D-78467 Konstanz,
Germany

CE 0120

Emergency contact information:
For chemical emergency
(spill, leak, fire, exposure or accident)
Call ChemTrec - day or night
Emergency phone no. 1.800.424.9300

SECTION I - PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME

ProRoot MTA Root Canal Repair Material.

SECTION 2 - COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL FAMILY

Calcium silicate compounds, calcium compounds containing aluminum oxide and bismuth oxide make up the majority of this product.

Major compounds:

$3\ CaO\text{-}SiO_2$	Tricalcium silicate
Bi_2O_3	Bismuth oxide
$2\ CaO\text{-}SiO_2$	Dicalcium silicate
$3\ CaO\text{-}Al_2O_3$	Tricalcium aluminate
$CaSO_4\text{-}2H_2O$	Calcium sulfate dihydrate or Gypsum

HAZARDOUS INGREDIENTS

Portland cement clinker (CAS# 65997-15- 1) - approximately 75% by weight
ACGIH TLV-TWA (1995-1996) = 10 mg total dust/m^3
OSHA PEL (8-hour TWA) = 50 million particles/ft^3

Gypsum (CAS# 10101-41-4) - approximately 5% by weight
ACGIH TLV-TWA(1995-1996) = 10 mg total dust/m^3
OSHA PEL (8-hour TWA) = 10 mg total dust/m^3
OSHA PEL (8-hour TWA) = 5 mg respirable dust/m^3

Bismuth Oxide (CAS# 1304-76-3) - approximately 20% by weight
OSHA - none published
ACGIH - none published

TRACE ELEMENTS/IMPURITIES CONTRIBUTING TO HAZARD

This product may contain minute trace amounts of potentially harmful chemicals if analyzed using sensitive analytical techniques. The product may contain up to 0.6% insoluble residue, some of which may be free, crystalline silica. Other trace constituents may include calcium oxide (also known as free lime or quick lime), free magnesium oxide, potassium and sodium sulfate compounds.

SECTION 3 - HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

ProRoot MTA Root Canal Repair Material is an off-white 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 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.

POTENTIAL HEALTH EFFECTS

Relevant routes of exposure:

Eye contact, skin contact, inhalation, and ingestion.

Effects resulting from eye contact:

Exposure to airborne dust may cause immediate or delayed irritation or inflammation.

Eye contact by larger amounts of dry powder or splashes of moist/wet material may cause effects ranging from moderate eye irritation to chemical burns and blindness in severe instances. Such exposures require immediate first aid (see Section 4) and medical attention to prevent significant damage to the eye.

Effects resulting from skin contact:

Discomfort or pain cannot be relied upon to alert a person to a hazardous skin exposure. Consequently, the only effective means of avoiding skin injury or damage involves minimizing skin contact, particularly contact with moist/wet material. Exposed persons may not feel discomfort until hours after the exposure and, in this case, significant injury may have already occurred.

Exposure to dry powder may cause drying of the skin with consequent mild irritation or more significant effects attributable to aggravation of other skin conditions. Dry powder contacting wet skin or exposure to moist or wet material may cause more severe skin effects due to caustic nature. Effects that are possible are thickening, cracking or fissuring of the skin. Prolonged exposure can cause severe skin damage in the form of (caustic) chemical burns.

Effects resulting from inhalation:

ProRoot MTA Root Canal Repair Material may contain trace amounts of free crystalline silica. Prolonged exposure to respirable free crystalline silica may aggravate other lung conditions. It also may cause delayed lung injury including silicosis, a disabling and potentially fatal lung disease, and/or other diseases. (Also see "Carcinogenic Potential" below.)

Exposure to the powder may cause irritation to the moist mucous membranes of the nose, throat and upper respiratory system. It may also leave unpleasant deposits in the nose, if large amounts of the powder are airborne and breathed in.

Effects resulting from ingestion:

Although small quantities of dust are not known to be harmful, ill effects are possible if larger quantities are consumed. Take care not to eat any of this product.

Carcinogenic potential:

The ingredients used to manufacture ProRoot MTA Root Canal Repair Material are not listed as carcinogens by NTP, OSHA or IARC. It may, however, contain trace amounts of substances listed as carcinogens by these organizations.

Crystalline silica, a potential trace level contaminant, is now classified by IARC as a known human carcinogen (Group I). NTP has characterized respirable silica as "reasonably anticipated to be a carcinogen."

Medical conditions which may be aggravated by inhalation or dermal exposure:

Pre-existing upper respiratory and lung diseases.

SECTION 4 - FIRST AID MEASURES

EYES

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 OF AIRBORNE DUST

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.

SECTION 5 - FIRE-FIGHTING MEASURES

EXTINGUISHING MEDIA

None required; does not burn

SPECIAL FIRE-FIGHTING PROCEDURES

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.)

HAZARDOUS COMBUSTION PRODUCTS

None

UNUSUAL FIRE AND EXPLOSION HAZARDS

None

SECTION 6 - ACCIDENTAL RELEASE MEASURES

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.

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.

Dispose of waste material according to local, state and federal regulations.

SECTION 7 - HANDLING AND STORAGE

HANDLING

Promptly remove dusty clothing or clothing which is wet with product and launder before reuse. Wash thoroughly after exposure to dust or wet product mixtures or fluids. Use local exhaust ventilation to minimize airborne dusts. Avoid contact with ammonia, ammonia nitrate and chlorine or chlorine containing items.

STORAGE

Store in dry area. Normal temperatures and pressures do not affect the material. Store away from food and drinks. Do not store near ammonia, ammonia nitrate and chlorine or chlorine containing items.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

RESPIRATORY PROTECTION

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

Use NIOSH/MSHA-approved (under 30 CFR 11) or NIOSH-approved (under 42 CFR 84) respirators in poorly ventilated areas, if an applicable exposure limit is exceeded, or when dust causes discomfort or irritation. (Advisory: Respirators and filters purchased after July 10, 1998 must be certified under 42 CFR 84.)

Portland cement clinker(CAS# 65997-15- 1) - approximately 75% by weight
ACGIH TLV-TWA (1995-1996) = 10 mg total dust/m^3
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Bismuth Oxide (CAS# 1304-76-3) - approximately 20% by weight
OSHA - none published
ACGIH - none published

EYE PROTECTION

When engaged in activities where dust or wet product could contact the eye, wear safety glasses with side shields or goggles. In extremely dusty environments or unpredictable environments, wear unvented or indirectly vented goggles to avoid eye irritation or injury. Contact lenses should not be worn when working with ProRoot MTA Root Canal Repair Material.

SKIN PROTECTION

Prevention is essential to avoiding potentially severe skin injury. Avoid contact with dry or wet product. If contact occurs, promptly wash affected area with soap and water. Where prolonged exposure to unhardened product might occur, wear impervious clothing and gloves to eliminate skin contact. Where required, wear boots that are impervious to water to eliminate foot and ankle exposure.

Do not rely on barrier creams; barrier creams should not be used in place of gloves.

Periodically wash areas contacted by dry powder or wet material with a pH-neutral soap. Wash again at the end of the work. If irritation occurs, immediately wash the affected area and seek treatment. If clothing becomes saturated with wet material, it should be removed and replaced with clean dry clothing.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Physical State .....Solid (Powder)
Color.....Off-White
Odor .....No distinct odor
pH (in water) (ASTM D 1293-95).....12 to 13
Boiling point.....Not applicable [i.e., >1000°C(1800°F)]
Melting point .....Not applicable
Flash point [provide method used] .....None
Lower Explosive Limit .....None
Upper Explosive Limit .....None
Auto ignition temperature .....Not combustible
Solubility in water.....Slightly soluble (0. 1 to 1.0 %)
Vapor pressure.....Not applicable
Vapor density .....Not applicable
Specific gravity (H_20 = 1.0) .....4 to 4.5
Evaporation rate.....Not applicable

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SECTION 10 - STABILITY AND REACTIVITY

STABILITY

Stable

CONDITIONS TO AVOID

Avoid unintentional contact with water to prevent premature setting/curing.

INCOMPATIBILITY

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

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

HAZARDOUS POLYMERIZATION

Hazardous polymerization will not occur.

SECTION 11 - TOXICOLOGICAL INFORMATION

No toxicological testing of this special product has been done.

SECTION 12 - ECOLOGICAL INFORMATION

ECOTOXICITY

No recognized unusual toxicity to plants or animals.

SECTION 13 - DISPOSAL CONSIDERATIONS

Dispose of waste material according to local, state and federal regulations.

Dispose of packaging in an approved landfill or incinerator.

SECTION 14 - TRANSPORTATION INFORMATION

Hazardous materials description/proper shipping name ProRoot MTA Root Canal Repair Material is not hazardous under U.S. Department of Transportation (DOT) regulations.

DOT 49 CFR:_____

IMDG:_____

IATA - DGR: _____

UN Classification No. _____

SECTION 15 - REGULATORY INFORMATION

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 aluminum oxide and gypsum) are considered to be "hazardous chemicals" under this regulation; thus, the product should be part of hazard communication program(s).

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.

Status under TSCA (as of May 1997)

Some substances in the major component of ProRoot MTA Root Canal Repair Material are on the TSCA inventory list.

Status under the Federal Hazardous Substances Act

The major component of ProRoot MTA Root Canal Repair Material (calcium silicate compounds and calcium compounds containing aluminum oxide and gypsum) is a "hazardous substance" subject to statutes promulgated under the subject act.

Status under California Proposition 65

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 waring in the absence of definitive testing to prove that the defined risk do not exist.

Status under Canadian Environmental Protection Act

Not listed.

Status under 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).

SECTION 16 - OTHER INFORMATION

PREPARED BY/DATE

Jim Greenburg, February 1, 2002

DATE OF PREVIOUS MSDS

None

MSDS NUMBER

None

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 material 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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SECTION I - PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME

ProRoot MTA Root Canal Repair Material Water.

This product contains no hazardous ingredients.