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SECTION 1: Identification of the substance/preparation and of the company/undertaking

1.1- Product Identification			
Product Name	: Prime MTA Bioceramic Root Canal Sealer		
Product Code	: MTS		
Product Description	: Bioceramic Root Canal Permanent Filling Material		
Packing Available	: 3g		
1.2- Relevant identified uses of the substance or mixture and uses advised against			
Relevant identified uses	: Bioceramic Root Canal Permanent Filling Material. Used by dental professional		
	only. For dental use only.		
1.3- Details of the supplier of the safety data sheet			
Manufacturer	: Prime Dental Products Pvt Ltd.		
Address	: Plot No. A-148, Road No. 24, MIDC, Wagle Industrial Estate, Thane (West)-		
	400604, Maharashtra, India		
Email	: <u>info@prime-dental.in</u>		
Web	: <u>www.prime-dental.in</u>		
1.4- Emergency contact details			
Telephone	: +919272235922 / +919272235925		

SECTION 2: Composition/information on ingredients

2.1- Mixture

<u>Component</u>	<u>C.A.S.</u>	EINECS	Classification*	Weight%	<u>LD50</u>
Tricalcium silicate	12168-85-3	Not Available	H317, H319	15-45%	Oral Rat –
Dicalcium silicate	1344-95-2				1848 mg/kg
Tricalcium aluminate	12042-78-3				

All mentioned components are premixed part of Portland Cement therefore they have a common classification, weight% and LD50 value

*For wording of the listed 'R' phrases and 'H' statements see section 16

SECTION 3: Identification of Hazards

3.1- Hazard Description : H317, H319

3.2- Information concerning to particular hazards to man and environment:

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation

SECTION 4: First aid measures

4.1- Description of first aid measures

Contact with skin: Wash with pH neutral soap and water. Get medical attention if irritation develops or persists. **Contact with eyes**: Flush eyes with plenty of water. Get medical attention, if irritation persists. **Ingestion**: Rinse mouth with water. Give water for drinking. DO NOT induce vomiting. Consult a physician if ingested in large amounts.

Inhalation: Supply fresh air. Get medical attention, if irritation persists.

SECTION 5: Fire-Fighting Measures

5.1- Conditions of Flammability: Non-Combustible.

5.2- Recommended extinguishers: There is no restriction on the type of extinguisher which may be used. Use extinguishing media suitable for surrounding area.

5.3- Extinguishers not to be used: There is no restriction on the type of extinguisher.

5.4- Risks arising from combustion: None

5.5- Protective equipment: Firefighters should always wear full protective gear to fight any fire. Prevent spillage from entering drains or water courses.

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SECTION 6: Accidental Release Measures

6.1 Measures for personal safety: Wear protective clothing

6.2 Measures for environmental protection: Do not allow product to reach sewage system or any water courses.

6.3 Measures for cleaning/collecting: Collect the material using a scoop. Dispose of waste material according to local, state and federal regulations. Collect the moist product and store in appropriate containers.

SECTION 7: Handling and Storage

7.1-Handling product: Is intended for dental use only.

7.2- Information for safe handling: No special measures required. Observe normal care for working with chemicals.

7.3- Information about fire and explosion protection: No special measures required.

7.4- Storage requirements to be met by storerooms and receptacles: Store only in the original receptacle. 7.5- Information about storage in one common storage facility: Store away from foods and drinks. Do not

store next to ammonia, ammonium nitrate, chlorine or chlorine-containing items.

7.6- Further information about storage conditions: Protect from heat and direct sunlight.

SECTION 8: Exposure Controls/Personal Protection

8.1- Additional information about design of technical facilities: No further data; see section 7.

- 8.2- Ingredients with limit values that require monitoring at the workplace: No known
- 8.3- Personal protective equipment:

a. Respiratory protection	: Not required if room is well ventilated		
b. Protection of hands	: The glove material has to be impermeable and resistant to the product/ the		
	substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.		
c. Eye protection	: Safety glasses		
d. Body protection	: Protective work clothing		

SECTION 9: Physical and Chemical Properties

9.1- Physical Properties:

Form : Paste Color : Greenish-Yellow Odour : None

9.2- Chemical Properties:

Melting point/Melting range	: Undetermined
Boiling point/Boiling range	: Undetermined
Ignition temperature	: Undetermined
Flash point	: Undetermined
Self-igniting	: Undetermined
Danger of explosion	: Product does not present an explosion hazard.
Density	: Undetermined
Solubility in / Miscibility with Water	: Low

SECTION 10: Stability and Reactivity

10.1- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

10.2- Reactions: Contact with the liquid or water will result the hydration of the product and formation of calcium hydroxide (caustic).



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10.3 Dangerous decomposition products: No dangerous decomposition products known

SECTION 11: Stability and Reactivity

11.1- Acute toxicity	: Not Available
11.2- Primary irritant effect	: Nil
11.3- On the skin	: May cause skin irritation
11.4- On the eye	: Causes irritating effect.
11.5- Sensitization	: No sensitizing effects known.

SECTION 12: Ecological Information

12.1- Environmental data: Not Available

SECTION 13: Disposal Consideration

13.1- Product Recommendation: Must not be disposed together with household garbage. Do not allow product to reach sewage system.

13.2- Uncleaned Packaging Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport Information

14.1- Air (ICAO/IATA)Primary Hazard Class/Division: No classification14.2- Road (RID/ADR): No classificationPrimary Hazard Class/Division: No classification14.3- Vessel (IMO/IMDG/RID/ADR)Primary Hazard Class/Division: No classification

SECTION 15: Regulatory Information

15.1- Safety, health and environmental regulations/legislation specific for the substance or mixtureGeneral comments: Please refer to Medical Devices Directive 93/42/EEC.15.2- Chemical safety assessment: See Section 11

SECTION 16: Additional Information

16.1- 'R' phrases and 'H' statement:

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

16.2- Prepared by: Tanay Thakkar

16.3- Manufacturer Disclaimer: For Dental Use Only, Use as directed.

The information and recommendations are taken from sources (raw material MSDS(s) and manufacturer's knowledge) believed to be accurate; however, Prime Dental Products Pvt Ltd, makes no warranty with respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof. Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.