

Material Safety Data Sheet

MTA BioRep

1. Product and manufacturer information

Product Name: MTA BioRep

Application/Use: bioceramic endodontic reparative cement, with high plasticity, for endodontic complications. For dental use only

Manufacturer:

ITENA CLINICAL

83, Avenue Foch

75116 Paris –France

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2. Composition / Information of Hazardous Ingredients


CAS n°/ EC n°	Reach registration n°	% (weight)	Name	Classification according to Regulation (EC) n° 1278/2008 (CLP)
12168-85-3	NA	45-55	3CaO.SiO ₂ Tricalcium Silicate	Skin Irrit. 3 H315 Eye Irrit. 2 H319
10034-77-2	NA	10-15	2CaO.SiO ₂ Dicalcium Silicate	
12042-78-3	NA	5-12	3CaO.Al ₂ O ₃ Tricalcium Aluminate	
1305-78-8	NA	1-5	CaO Calcium Oxide	
7790-75-2	NA	20-30	CaWO ₄ Calcium tungstate	

3. Hazards Identification

GHS Classification

Hazard/Danger Classification

Health hazards

Hazard Class	Category	Signal word	Hazard Statement	Pictogram
Skin irritation	2	Warning	Causes skin irritation	
Eye irritation	2A	Warning	Causes serious eye irritation	
Respiratory irritation	3	Warning	May cause respiratory irritation	

Precautionary Statements

P261 – Avoid breathing dust

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 water and soap

P304+P340 – If inhaled: remove person to fresh air and keep comfortable for breathing

P305+P351 – If an eyes: rinse cautiously with water for several minutes

P332+P313 – If skin irritation occurs: get medical advice/attention

P337+P313 – If eye irritation occurs: get medical advice/attention

Physical Hazards

This product reacts in contact with moisture and water producing a strong alkaline material

Environment hazard

Not applicable

4. First Aid Measures

Routes of exposure	Most important symptoms/effects, acute and delayed	First aid treatment
Skin	Skin irritation	Wash with plenty of cool water and pH-neutral soap. Seek medical treatment in all cases of prolonged exposure to wet material, freshly cured product, or prolonged wet skin exposure to the dry powder.
Eye	Severe eye irritation	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. If eye irritation occurs: Get medical advice /attention.
Inhalation	Irritation to the moist mucus	Remove person to fresh air and

	membranes of the nose, throat and upper respiratory system	keep comfortable for breathing. Inhalation of large amounts of MTA BioRep requires immediate medical attention.
Ingestion	Irritation to the digestive tract	Do not induce vomiting. If person is conscious, use water to rinse out the mouth and have the person drink plenty of water.

5. Fire-Fighting Measures

Conditions of Flammability: non Combustible.

Suitable Extinguishing Media: there is no restriction on the type of extinguisher which may be used. Use extinguishing media suitable for surrounding area.

Unsuitable Extinguishing Media: there is no restriction on the type of extinguisher.

Specific Hazards Arising From the Product: none.

Advice for Fire-fighters: firefighters should always wear full protective gear to fight any fire. 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 as described in Section 8. Collect dry material using a scoop. Avoid actions that cause dust to become airborne. Avoid inhalation of dust and contact with skin.




7. Handling and Storage

Precautions for Safe Handling: handle with care. Avoid direct contact with the skin. Avoid generation of dust. Avoid contact with ammonia, ammonium nitrate, chlorine or chlorine-containing items.

Conditions for Safety Storage: store in a dry place. Standard temperature and pressure do not affect the product. Store away from foods and drinks. Do not store next to ammonia, ammonium nitrate, chlorine or chlorine-containing items.

8. Exposure Controls/ Personal Protection

Control paramters	The product does not contain any relevant quantities of materials with critical values that have to be monitored at the work place	
Appropriate engineering controls	Well ventilation	
Individual protection measures, such as personal protective equipment (PPE)	Eye/face protection	Safety glasses. Activities, in which the powder or wet product may

		<p>come into contact with eyes, use safety glasses. Be careful when using contact lenses when working with MTA BioRep.</p>
	<p>Skin protection</p> 	<p>Protective work clothing. Avoid contact with a dry or damp. In cases of prolonged exposure with a dry (powder), use waterproof clothing and gloves to avoid skin broker. When required, use waterproof boots to moisture to eliminate exposure of toe and heel. In case of skin irritation, wash the affected area and, if necessary, seek medical attention.</p>
	<p>Respiratory protection</p> 	<p>Surgical face mask Avoid actions that may lead to the formation of dust. Use proper mask for particulate material.</p>

9. Physical/ Chemical Properties

Appearance: solid (powder), white
 Odor: no distinct odour
 Odor Threshold: NA
 pH: 10-12
 Melting point/Freezing Point: NA
 Initial Boiling Point and Boiling Range: NA
 Flash Point: NA
 Evaporation Rate: NA
 Flammability: NA
 Upper/Lower
 Flammability/ExplosiveLimits: NA
 Vapour Pressure: NA
 Vapour Density: NA
 Relative Density : NA
 Solubility (with water): slightly soluble
 Partition Coefficient n-octanol/water: NA
 Auto-ignition Temperature: NA
 Decomposition Temperature: NA
 Viscosity Temperature: NA

10. Stability and Reactivity

Reactivity: contact with the liquid or water will result the hydration of the product and formation of calcium hydroxide (caustic).

Chemical Stability: product stable in normal conditions.

Possibility of Hazardous Reactions: not Available

Conditions to Avoid: avoid contact with water to prevent premature setting.

Incompatible Materials: acids, ammonia, nitrate, ammonium salts, aluminum metal and chlorine.

Hazardous Decomposition Products: decomposition will not occur spontaneously

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: MTA BioRep 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.

Likely Routes of Exposure	Signs and Symptoms	Single, Repeated, or Lifetime Exposure	Severity (Mild, Moderate, Severe)	Acute and Chronic Health Effects	Target Organs	LD50 Testing Data (as applicable)	LC50 Testing Data (as applicable)
Eye	Irritation or Inflammation	Single	Moderate	Blindness in severe cases.	Eye	NA	NA
Skin	Mild Irritation, skin dryness	Single	Mild	Severe skin damage.	Skin	NA	NA
Inhalation	Irritation to moist mucous membranes of the nose, throat and upper respiratory system.	Repeated	Mild	Lung injury can occur.	Mucous membranes of the nose, throat and upper respiratory system.	NA	NA
Ingestion	Internal discomfort or irritation to the digestive tract.	Single	Mild	Ill effects are possible if large amounts are consumed.	Digestive system	NA	NA

Medical conditions aggravated by exposure: pre-existing upper respiratory and lung diseases

Carcinogenicity: ingredients not listed as carcinogens

12. Ecological Information

Toxicity: not available

Persistence and Degradability: not available

Bioaccumulative Potential: not available

Mobility in Soil: not available

Other Adverse effects: not available

13. Disposal Considerations

Waste Treatment Methods: avoid creation or breathing dust during disposal. Avoid contact with skin and eyes. Refer to Section 8 for personal protection measures. Dispose of waste and contaminated product in a suitable sealed container. Dispose of product according to local and federal regulations. Do not dispose of product down drains or from entering sewage systems.

Physical/Chemical Properties Affecting Disposal Options: no known precautions.

Special Precautions for Incineration or Landfill: NA

14. Transport Information

UN Number: NA

UN Proper Shipping Name: MTA REPAIR HP

Transport Hazard Class(es): NA

Environmental Hazards: NA

Precautions for User: NA

Transport in Bulk (According to Annex II of MARPOL 73/789 and IBC Code): NA

15. Regulatory Information

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 MTA BioRep (calcium silicate compounds are considered to be “hazardous chemicals” under this regulation; thus, the product should be part of hazard communication program(s).

Hazard Category under SARA (Title III), Section 311 and 312: The major components of MTA BioRep (calcium silicate compounds) qualify as “hazardous substances” with delayed health effects.

Status under REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labeling 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)

16. Other Information

Date of Preparation: 12-12-2016

The information contained in this sheet is based on our knowledge on the date indicated above. This information refer only to the indicated product and of not constitute guarantee for a particular quality. The user is fully responsible to adopt the due precautions to protect property and people against any damages, which might derive from such handling and use. We recommend the user to carefully observe the destination and the form of use of the product, using according to the instructions.