



MTA BIOREP

Safety Data Sheet

According to Regulation (EC) No. 1907/2006 (amended by Regulation (EU) No. 2015/830)

Version : 1

Version date : 02/05/2018

Language: EN

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

1.1. Product identifier

Trade name / designation : MTA BIOREP
Article No (user) : MTA-BRP2.2/MTA-BRP5.5

1.2. Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses : Dental products
Uses advised against : No data available

1.3. Details of the supplier of the safety data sheet

Supplier : ITENA CLINICAL
Street: 83, Avenue Foch
Postal code / City: 75116 Paris
Country: France
Telephone: [+33 1 45 91 30 06](tel:+33145913006)
Telefax: [+ 33 1 45 91 61 31](tel:+33145916131)
E-mail: contact@iten-clinical.com

1.4 Emergency Telephone Number

In England and Wales: dial 111 (NHS 111), In Scotland: dial 111 (NHS 24), In Northern Ireland: Contact your local GP or pharmacist during normal hours. During GP Out-of-Hours (www.gpoutofhours.hscni.net/): Belfast HSC Trust, (North & West) 028 9074 4447, (South & East) 028 9079 6220 South Eastern HSC Trust, (North Down & Ards) 028 9182 2344, (Lisburn & Downpatrick) 028 9260 2204, Dalriada Urgent Care (Northern Trust area) 028 2566 3500, Southern HSC Trust 028 3839 9201, Western Urgent Care 028 7186 5195 Not available

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Classification	Hazard statements	
 Skin Irrit. 2	H315	Causes skin irritation
 Eye Irrit. 2	H319	Causes serious eye irritation

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms	
Signal word	Warning
Product identifiers	-
Hazard Statements	H315 - Causes skin irritation H319 - Causes serious eye irritation
Supplemental Hazard information (EU)	-
Precautionary Statements - General	-
Precautionary Statements - Prevention	P261 - Avoid breathing dust/fume/gas/mist/vapours/spray. P264 - Wash ... thoroughly after handling. P280 - Wear protective gloves/protective clothing/eye protection/face protection.
Precautionary Statements - Response	P302+P352 - IF ON SKIN: Wash with plenty of water/... P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332+P313 - If skin irritation occurs: Get medical advice/attention.
P337+P313 - If eye irritation persists: Get medical advice/attention.

Precautionary Statements - Storage
Precautionary Statements - Disposal

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2.3. Other hazards

Not available

SECTION 3: Composition/information on ingredients

3.1. Substances

This product does not contain any hazardous ingredients at or above regulated thresholds.

3.2. Mixtures

The mixture does not contain any substances classified as Substances of Very High Concern (SVHC) by the European CHemicals Agency (ECHA) under article 57 of REACH: <http://echa.europa.eu/fr/candidate-list-table>

3.3. Remark

Text phrases and H- EUH-: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information	: In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible). Keep affected person warm, still and covered. Do not leave affected person unattended.
Following inhalation	: Remove person to fresh air and keep comfortable for breathing. In case of inhalation of large quantities of MTA BIOREP, seek immediate medical attention
Following skin contact	: Wash with soap and water. Change contaminated, saturated clothing. Take off contaminated clothing. In case of skin irritation, consult a physician.
Following eye contact	: In case of eye irritation consult an ophthalmologist. Rinse immediately carefully and thoroughly with eye-bath or water. Remove contact lenses, if present and easy to do. Continue rinsing.
Following ingestion	: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Rinse mouth immediately and drink plenty of water.
Self-protection of the first aider	: First aider: Pay attention to self-protection!

4.2. Most important symptoms and effects, both acute and delayed

Effects	: Causes skin irritation. Causes serious eye irritation. Inhalation of dust may cause irritation of the respiratory system.
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4.3. Indication of any immediate medical attention and special treatment needed

Notes for the doctor	: Treat symptomatically.
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SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Foam Extinguishing powder Carbon dioxide (CO2) Sand
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5.2. Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing.

5.4. Additional information

Do not inhale vapors and fumes. Co-ordinate fire-fighting measures to the fire surroundings. Move undamaged containers from immediate hazard area if it can be done safely. Use caution when applying carbon dioxide in confined spaces. carbon dioxide can displace oxygen. Use water spray jet to protect personnel and to cool endangered containers. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protection equipment. Remove persons to safety. Provide adequate ventilation.

6.2. Environmental precautions

Ensure that waste is collected and contained.

6.3. Methods and material for containment and cleaning up

Treat the recovered material as prescribed in the section on waste disposal. Collect in closed and suitable containers for disposal. Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Safe handling: see section 7 Disposal: see section 13 Personal protection equipment: see section 8

6.5. Additional information

Not available

SECTION 7: Handling and Storage

7.1. Precautions for safe handling

Protective measures

Avoid contact with skin, eyes and clothes. Wear personal protective clothing (see section 8). Avoid breathing dust.

Advices on general occupational hygiene

Wash hands before breaks and after work. Remove contaminated, saturated clothing. Wash contaminated clothing before reuse.

7.2. Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry, cool, and well-ventilated place. Keep container in upright position in order to prevent leakage.

Requirements for storage rooms and vessels

Avoid contact with ammonia, ammonium nitrate, chlorine or products containing chlorine

Advice on joint storage

Keep away from food, drink and animal feedingstuffs.

7.3. Specific end uses

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Does not contain substances above concentration limits fixing an occupational exposure limit.

8.2. Exposure controls

Appropriate engineering controls

Technical measures and the application of suitable work processes have priority over personal protection equipment. Provide adequate ventilation as well as local exhaustion at critical locations.

Personal protection equipment

Not available

Eye/face protection

- : Eye glasses Dust protection eye glasses
Suitable eye protection: Wear eye protection equipment. For activities in which the powder or the moist product may come into contact with the eyes Be careful when wearing contact lens

Skin protection

- : Wear protective clothing.
Hand protection: Suitable gloves type: Wear protective gloves.
Hand protection: Additional hand protection measures.: Do not wear gloves near machines and rotating tools. Use gloves only once.
Hand protection: Remark: When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with

the supplier of these gloves. Breakthrough times and swelling properties of the material must be taken into consideration.

Hand protection: Disposable gloves

Body protection: Suitable protective clothing: Chemical protection clothing

Body protection: Chemical protection clothing

Respiratory protection : Dust formation Surgical mask

Suitable respiratory protection apparatus: Wear respiratory protection. Use an appropriate mask for particles

Additional measures for respiratory protection: Avoid generation of dust.

Remark: The filter class must be suitable for the maximum contaminant concentration (gas/vapour/aerosol/particulates) that may arise when handling the product. If the concentration is exceeded, self-contained breathing apparatus must be used. Use only respiratory protection equipment with CE-symbol including four digit test number. Observe the wear time limits as specified by the manufacturer.

8.3. Additional information

Not available

SECTION 9: Physical and chemical Properties

9.1. Information on basic physical and chemical properties

Physical state:	Solid
Colour:	white
Odour:	No specific smell
Odour threshold:	
pH:	10
Melting point/freezing point:	
Initial boiling point and boiling range:	°C
Flash point:	°C
Evaporation rate:	
Flammability:	
Upper/lower flammability or explosive limits:	
Vapour pressure:	Not available
Vapour density:	
Relative density:	
Solubility(ies):	Slightly soluble
Partition coefficient: n-octanol/water (Log KOC):	
Auto-ignition temperature:	
Decomposition temperature:	
Viscosity:	
Explosive properties:	
Oxidising properties:	

9.2. Other safety information

Not available

SECTION 10: Stability and Reactivity

10.1. Reactivity

Contact with liquid or water will result in product hydration and formation of calcium hydroxide (caustic)

10.2. Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

10.3. Possibility of hazardous reactions

Not available

10.4. Conditions to avoid

Avoid contact with water to avoid premature mixing.

10.5. Incompatible materials

Acid Ammonia Nitrate Ammonium salts Aluminum metal Chlorine

10.6. Hazardous decomposition products

No known hazardous decomposition products.

10.7. Additional information

Not available

SECTION 11: Toxicological information

11.1. Acute oral toxicity

Mix data

Not available

Substances

Not available

11.2. Acute skin toxicity

Mix data

Not available

Substances

Not available

11.3. Acute inhalation toxicity

Mix data

Not available

Substances

Not available

11.4. Skin corrosion

Mix data

Not available

Substances

Not available

11.5. Eyes damage

Mix data

Not available

Substances

Not available

11.6. Skin sensitization

Mix data

Not available

Substances

Not available

11.7. STOT RE

Mix data

Not available

Substances

Not available

11.8. STOT SE

Mix data

Not available

Substances

Not available

11.9. Carcinogenicity

Mix data

Not available

Substances

Not available

11.10. Reproduction and development toxicity

Mix data

Not available

Substances

Not available

11.11. Genotoxicity

Mix data

Not available

Substances

Not available

Additional information

A single short-term exposure to dry powder is not likely to cause serious harm. However, exposure of a sufficient amount of sufficient duration (single or multiple) to a moist product can cause a serious, potentially irreversible destruction of tissues (skin or eye) in the form of chemical (caustic) burns, including third degree burns. The same type of tissue destruction may occur if wet or moist areas of the body are exposed for a sufficient period of time to the dry product. Pre-existing respiratory and pulmonary diseases may be aggravated by exposure to the product

Routes of exposure	Signs et symptoms	Single, repeated or lifetime exposure	Severity (mild, moderate, severe)	Acute and chronic health effects	Target organs
Eyes	Irritation of inflammation	Single	Moderate	Blindness in severe cases	Eyes
Skin	Mild irritation Skin dryness	Single	Mild	Severe skin damage	Skin
Inhalation	Mucous membranes irritation	Repeated	Mild	Lung injury can occur	Mucous membranes
Ingestion	Irritation of digestive tract	Repeated	Mild	Ill effects possible if large amounts are consumed	Digestive system

SECTION 12: Ecological information

12.1. Toxicity

Based on available data, the classification criteria are not met.

12.2. Persistence and degradability

The product has not been tested.

12.3. Bioaccumulative potential

The product has not been tested.

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

No data available

12.6. Other adverse effects

No data available

12.7. Additional ecotoxicological information

Not available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal

Waste codes / waste designations according to EWC / AVV: The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process.

Waste treatment options: Appropriate disposal / Product: Dispose of waste according to applicable legislation. Do not allow to enter into surface water or drains.

Waste treatment options: Appropriate disposal / Package: Non-contaminated packages must be recycled or disposed of. Handle contaminated packages in the same way as the substance itself. Dispose of waste according to applicable legislation.

Remark: For recycling, contact manufacturer.

13.2. Additional information

Not available

SECTION 14: Transport information

14.1. UN number

Not available

14.2. UN proper shipping name

Not available

14.3. Transport hazard class(es)

Not available

14.4. Packing group

Not available

14.5. Environmental hazards

Not available

14.6. Special precautions for user

Not available

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not available

14.8. Additional information

Not available

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

This SDS has been established in accordance with REACH regulation, including its amendments: REACH Regulation (EC) No 1907/2006. This SDS has been established in accordance with CLP regulation, including its amendments: CLP Regulation EC No. 1272/2008.

Not available

15.2. Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier. For this substance/ mixture a chemical safety assessment has been elaborated. For this mixture, the relevant data of the Substances' Chemical safety assessment are integrated in the sections of the SDS.

15.3. Additional information

Not available

SECTION 16: Other information

Date de création:	02/05/2018
Date de version:	02/05/2018
Date d'impression:	17/05/2018

16.1. Indication of changes

Not applicable (first edition of the MSDS).

16.2. Abbreviations and acronyms

ADN / ADNR: Regulations concerning the transport of dangerous substances in barges on the waterways. ADR / RID: European Agreement concerning the International Carriage of Dangerous Goods by Road / Regulations concerning the international carriage of dangerous goods by rail. CAS: Chemical Abstract Service Number CLP: Classification, labeling and packaging IATA: International Air Transport Association IMDG: International Maritime Dangerous Goods Code DPD Dangerous Preparation Directive UN number: United Nations number No EC: European Commission Number VPvB: very persistent and very bioaccumulative substances

16.3. Key literature references and sources for data

No data available

16.4. Classification for mixtures and used evaluation method according to regulation (EC) 1272/2008 [CLP]

Classification of the mixture is in accordance with the evaluation method described in Regulation (EC) No 1272/2008.

16.5. Relevant R-, H- and EUH-phrases (Number and full text)

16.6. Training advice

Refer to Sections 4, 5, 6, 7 and 8 of this safety data sheet.

16.7. Additional information

Not available

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