

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

1.1. Product identifier

Trade name / designation : MTA BIOSEAL.
Article No (user) : MTA-BSEAL

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

Relevant identified uses : Dental products.

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@itena-clinical.com



1.4 Emergency Telephone Number

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	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.

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 occurs: Get medical advice /attention.
P362+P364 – Take off contaminated clothing and wash it before reuse

Precautionary Statements - Response
 Precautionary Statements - Storage
 Precautionary Statements - Disposal -

2.3. Other hazards

Adverse human health effects and symptoms

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance	C (%)	Reach Registration	Classification
Salicytate Resin CAS N°:119-36-8	20.0% ≤C≤ 25.0%	NA	Skin Irrit. 2 H315 Eye irrit. 2A H319
Diluent Resin CAS N°: 1077-56-1	20.0% ≤C≤ 25.0%	NA	
Mineral Trioxide Aggregate : - Tricalcium silicate - Dicalcium silicate - Tricalcium aluminat - Calcium oxide CAS N°:12168-85-3 CAS N° : 10034-77-2 CAS N° : 12042-78-3 CAS N° : 1305-78-8	20.0% ≤C≤ 25.0%	NA	
Calcium Tungstate CAS N° : 7790-75-2	20.0% ≤C≤ 25.0%	NA	
Titanium Dioxide CAS N° : 13463-67-7	1.0% ≤C≤ 10.0%	NA	
Silicon Dioxide CAS N° : 69012-6462	1.0% ≤C≤ 5.0%	NA	

3.2. Mixtures

Not available

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).
 Following inhalation : Remove person to fresh air and keep comfortable for breathing. Inhalation of large amounts of MTA BIOSEAL requires immediate medical attention.
 Following skin contact : In case of skin irritation, consult a physician. After contact with skin, wash immediately with plenty of water and soap.
 Following eye contact : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. If eye irritation occurs, get medical advice /attention.
 Following ingestion : Do not induce vomiting. If person is conscious, use water to rinse out the mouth and have the person drink plenty of water.

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

Not available

4.3. Indication of any immediate medical attention and special treatment needed

Notes for the doctor : Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media suitable for the surrounding area.
Unsuitable extinguishing media : No restriction.

5.2. Special hazards arising from the substance or mixture

If heated, may produce carbon monoxide, carbon dioxide, metal oxides, sulfur oxides

5.3. Advice for firefighters

Not available

5.4. Additional information

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

Wear appropriate personal protective equipment to prevent contamination of skin, eyes and personal clothing as described in Section 8.
MTA BIOSEAL is a high viscosity paste, but will flow somewhat. Collect material using a scoop and place in a labeled plastic container

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

Collect material using a scoop and place in a labeled plastic container. Dispose of waste material according to local, state and federal 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

Avoid contact with skin, eyes and clothes. Sewers and ducts must be protected against the entry of the product.
No special measures are required for small quantities under normal and intended conditions of product use.

7.2. Conditions for safe storage, including any incompatibilities

Store in original container protected from direct sunlight in a dry, cool and well-ventilated area. Standard temperature and pressure do not affect the product. Store away from foods and drinks. Keep container tightly sealed.

7.3. Specific end uses

Observe instructions for use.

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Not available

8.2. Exposure controls

Appropriate engineering controls

Use only in well-ventilated areas.

Personal protection equipment



Eye/face Protection

: Safety glasses.
Be careful when using contact lenses when working with MTA BIOSEAL.

Skin protection



: Protective gloves have to be impermeable and resistant to the product.



Protective work clothing.
In case of skin irritation, wash the affected area and, if necessary, seek medical attention.

8.3. Additional information

Not available

SECTION 9: Physical and chemical Properties

9.1. Information on basic physical and chemical properties

Physical state:	Solid – High viscous paste
Colour:	Specific
Odour:	
Odour threshold:	Not available
PH:	10-12
Melting point/freezing point:	
Initial boiling point and boiling range:	N / A °C
Flash point:	N / A °C
Evaporation rate:	N / A
Flammability:	
Upper/lower flammability or explosive limits:	Not available
Vapour pressure:	
Vapour density:	N / A
Relative density:	
Solubility(ies):	Insoluble
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

No data available.

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

No hazardous reaction when handled and stored as recommended provisions.

10.4. Conditions to avoid

No special conditions to be avoided.

10.5. Incompatible materials

10.6. Hazardous decomposition products

Do not decompose when used for intended uses.

10.7. Additional information

Not available

SECTION 11: Toxicological information

Likely Routes of Exposure	Signs and Symptoms	Single, Repeated, or Lifetime Exposure	Severity	Acute and Chronic Health Effects	Target Organs	LD50	LC50
Eye	Irritation	Single & repeated	Moderate	Irritation & possible damage to cornea	Eyes	NA	NA
Skin	Irritation	Single & repeated	Mild	Severe skin damage	Skin	NA	NA
Inhalation	NA	NA	NA	NA	NA	NA	NA
Ingestion	Irritation	NA	Mild	Irritation	Digestive system	NA	NA

Additional information

No information available.

Substances

Not available

Data for mixture

No information available.

SECTION 12: Ecological information

12.1. Toxicity

Not established.

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 known significant effects or critical hazards.

12.7. Additional ecotoxicological information

Not available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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..

13.2. Additional information

Not available

SECTION 14: Transport information

14.5. Environmental hazards

No data available.

14.6. Special precautions for user

No data available.

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

No data 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

EU legislation

This product is a medical device according to EC directive 93/42.

Not available

15.2. Chemical Safety Assessment

No data available.

15.3. Additional information

Not available

SECTION 16: Other information

Creation date: 21/02/2018

Version date: 21/02/2018

Printing date: 21/02/2018

16.1. Indication of changes

Not applicable (first edition of the MSDS).

16.2. Abbreviations and acronyms

ADN / ADN R: 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)

H315 Causes skin irritation.

H319 Causes serious eye irritation.

16.6. Training advice

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

16.7. Additional information

Not available

The information given in this Safety Data Sheet is based on our present knowledge and on European and national regulations. This Safety Data Sheet describes safety requirements relative to identified uses, it doesn't guarantee all the product properties particularly in the case of non identified uses. The product mustn't be used for any uses other than those identified under heading 1. Since the user's working conditions are not known by us, it is the responsibility of the user to take all necessary measures to comply with legal requirements for specific uses and avoid negative health effects.