

Date issued: 03/05/2016

1. IDENTIFICATION

Product Identifier	
Trade Name	Product Identifier Number
MTA-FILLAPEX – Syringe 4gr	827
MTA-FILLAPEX – 12gr	8288
MTA-FILLAPEX – 30gr	826

Product Use: Root canal sealer.

Restrictions on Use: For dental use only.

Produced by:

ANGELUS INDÚSTRIA DE PRODUTOS ODONTOLÓGICOS LTDA - CNPJ 00.257.992/0001-37
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2. 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	

Precautionary Statements

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.

Physical Hazards

Not applicable.

Environment hazard

Not applicable.

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3. COMPOSITION / INFORMATION ON INGREDIENTS

CAS N°/ EC N°	Reach registration N°	% (weight)	Name	Classification according to Regulation (EC) No 1278/2008 (CLP)
119-36-8	NA	20-25	Salicylate Resin	Skin Irrit. 2 H315
NA	NA	20-25	Diluent Resin	
NA	NA	20-25	Mineral Trioxide Aggregate	
7790-75-2	NA	20-25	Calcium Tungstate	Eye irrit. 2A H319
13463-67-7	NA	1-10	Titanium Dioxide	
69012-64-2	NA	1-5	Silicon Dioxide	

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. If symptoms persist, get medical advice/attention.
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 respiratory system	Remove person to fresh air and keep comfortable for breathing. Inhalation of large amounts of MTA-Fillapex 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 the surrounding area.

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

Specific Hazards Arising From the Product: If heated, may produce carbon monoxide, carbon dioxide, metal oxides, sulfur oxides.

Advice for Fire-fighters: Firefighters should always wear full protective gear to fight any fire.

6. ACCIDENTAL LEAKAGE 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. MTA-Fillapex is a high viscosity paste, but will flow somewhat. Collect material using a scoop and place in a labeled plastic container.

Environmental Precautions: Prevent spillage from entering drains or water courses.

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.




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7. HANDLING AND STORAGE

Precautions for Safe Handling: MTA-Fillapex is intended for dental use only. Avoid direct contact with the skin. No special measures are required for small quantities under normal and intended conditions of product use.

Conditions for Safety Storage: 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.

8. EXPOSURE CONTROL / PROTECTION

Control Parameters	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 Protections Measures, Such as Personal Protective Equipment (PPE)	Eye/face Protection 	Safety glasses. Be careful when using contact lenses when working with MTA-FILLAPEX.
	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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	State: high viscous paste	Upper/Lower Flammability or Explosive Limits	NA
	Color: Base paste: yellow Catalyst paste: white		
Odour	Base paste: methyl salicylate odour Catalyst paste: No distinct odour	Vapour Pressure	NA
Odor Threshold	NA	Vapour Density	NA
pH	10-12	Relative Density	Base paste: 2.01 g/cm ³ Catalyst paste: 1.75 g/cm ³
Melting point/Freezing Point	NA	Solubility (in water)	Not soluble
Initial Boiling Point and	NA	Partition Coefficient n-	NA

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Boiling Range		octanol/water	
Flash Point	NA	Auto-ignition Temperature	NA
Evaporation Rate	NA	Decomposition Temperature	NA
Flammability	NA	Viscosity Temperature	NA

10. STABILITY AND REACTIVITY

Reactivity: There are no specific data related to reactivity available for this product.

Chemical Stability: Product stable in normal conditions.

Possibility of Hazardous Reactions: Under normal conditions of storage and use, hazardous polymerization will not occur.

Conditions to Avoid: There are no special conditions to be avoided.

Incompatible Materials: No specific data.

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-FILLAPEX is a high viscous paste that poses little immediate hazard. Irritating to skin and eye.

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	Single & Repeated	Moderate	Irritation and possible corneal damage due to the caustic nature of ingredients used in the product.	Eye	Not applicable	Not applicable
Skin	Irritation	Single & Repeated	Mild	Severe skin damage.	Skin	Not applicable	Not applicable
Inhalation	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Ingestion	Irritation	Not applicable	Mild	Irritation due to the caustic nature of ingredients used in the product.	Digestive system	Not applicable	Not applicable

Medical Conditions Aggravated by Exposure: Open sores and wounds of the skin.

Carcinogenicity: Ingredients not listed as carcinogens.

12. ECOLOGICAL INFORMATION

Toxicity: Not established

Persistence and Degradability: Not established

Bioaccumulative Potential: Not established

Mobility in Soil: Not established

Other Adverse effects: No known significant effects or critical hazards.

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13. DISPOSAL CONSIDERATIONS

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.

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

Special Precautions for Incineration or Landfill: NA

14. TRANSPORTATION INFORMATION

UN Number: NA

UN Proper Shipping Name: MTA-FILLAPEX

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

TSCA Inventory Status: All components are listed on the TSCA inventory.

SARA 304 RQ: Not applicable

Hazard Category under SARA (Title III), Section 311/312: None

SARA 313 (Toxic chemicals): None

Canadian Environmental Protection Act: This product is a medical device and not subject to chemical notification requirements.

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: 04-05-2016

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.

In case of doubts, request technical guidelines: **+55 43 2101-3200 or sac@angelus.ind.br**