

1. IDENTIFICATION

Product Identifier	
Trade Name	Product Identifier Number
BIO-C REPAIR (1 syringe with 0.5 g)	3861
BIO-C REPAIR (4 syringes with 0.5 g)	3863

Product Use: Bioceramic reparative material ready-to-use, intended to be used for patients requiring endodontic procedures, with the function of repairing endodontic complications in the tooth's root canal.

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:

According to GHS, it is not classified as a hazardous substance or mixture.

Health Hazards

Hazard Class	Category	Signal word	Hazard Statement	Pictogram
Skin reaction	1, 1A and 1B	Warning	Causes skin irritation	
Eye irritation	2A	Warning	Causes serious eye irritation	

Precautionary Statements:

P264 – Wash hands thoroughly after handling.

P265 – Do not touch eyes.

P280 – Wear protective gloves, protective clothing, eye protection.

P302 + P352 – IF ON SKIN: Wash with plenty of water.

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 + P317 – IF SKIN IRRITATION OCCURS: Get medical help.

P337 + P313 – If eye irritation persists: Get medical help.

Physical Hazards:

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

Environment hazard:

Not applicable.

3. COMPOSITION / INFORMATION ON INGREDIENTS

CAS N°/ EC N°	Reach registration N°	% (weight)	Name	Classification according to Regulation (EC) No 1278/2008 (CLP)
12168-85-3	235-336-9	20 – 25 %	Tricalcium silicate	May cause an allergic skin reaction (1, 1A e 1B) H317
1344-95-2	215-710-8	5 – 15 %	Dicalcium silicate	
12042-78-3	234-932-6	1 – 4 %	Tricalcium aluminate	Causes serious eye irritation (2) H319
Other Additives (radiopacifier, dispersing agent and fillers): According to the technical information, individually or in the mixture these materials are not classified as health hazards, thus do not contribute to the classification of these products.				

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 material, freshly cured product, or prolonged wet skin exposure to the paste.
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 membranes of the nose, throat and upper respiratory system	Remove person to fresh air and keep comfortable for breathing. Inhalation of large amounts of BIO-C REPAIR 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 the material using a scoop.

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

Methods and Material for Containment and Cleaning Up: Collect material using a scoop. Dispose of waste material according to local, state and federal regulations. Collect the moist product and store in appropriate containers.

7. HANDLING AND STORAGE

Precautions for Safe Handling: Handle with care. Avoid direct contact with the skin. 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 CONTROL / PERSONAL PROTECTION

Control Parameters	The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.	
Appropriate Engineering Controls	Well ventilation.	
Individual Protections Measures, Such as Personal Protective Equipment (PPE)	Eye/face Protection 	Safety glasses. Activities, in which the paste may come into contact with eyes, use safety glasses. Be careful when using contact lenses when working with BIO-C REPAIR.
	Skin Protection  	Protective work clothing. Avoid contact with the paste. In cases of prolonged exposure to paste, use waterproof clothing and gloves to avoid skin broker. When required, use waterproof boots to eliminate exposure of toe and heel. In case of skin irritation, wash the affected area and, if necessary, seek medical attention.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	State: Paste	Not available
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Date: 01/03/2023

	Color: Slightly yellow	Upper/Lower Flammability or Explosive Limits	
Odour	No distinct odour	Vapour Pressure	Not available
Odor Threshold	Not available	Vapour Density	Not available
pH	≥12	Relative Density	Not available
Melting point/Freezing Point	Not available	Solubility (with water)	Low
Initial Boiling Point and Boiling Range	Not available	Partition Coefficient n-octanol/water	Not available
Flash Point	Not available	Auto-ignition Temperature	Not available
Evaporation Rate	Not available	Decomposition Temperature	Not available
Flammability	Not available	Viscosity Temperature	Not available

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: BIO-C REPAIR is a paste that poses little immediate hazard. A single short-term exposure to the paste 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	Not available	Not available
Skin	Mild Irritation, skin dryness	Single	Mild	Severe skin damage	Skin	Not available	Not available
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.	Not available	Not available

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Ingestion	Internal discomfort or irritation to the digestive tract.	Single	Mild	The effects are possible if large amounts are consumed	Digestive system	Not available	Not available
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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 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: Not applicable.

14. TRANSPORT INFORMATION

UN Number: Not applicable.

UN Proper Shipping Name: BIO-C REPAIR.

Transport Hazard Class(es): Not applicable.

Environmental Hazards: Not applicable.

Precautions for User: Not applicable.

Transport in Bulk (According to Annex II of MARPOL 73/78⁹ and IBC Code): Not applicable.

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 BIO-C REPAIR (calcium silicate compounds are "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 BIO-C REPAIR (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: 30/03/23

The information contained in this sheet is based on our knowledge on the date indicated above. This information refers 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**