

1. IDENTIFICATION OF SUBSTANCES / PREPARATION AND COMPANY

Product Name: Totalfill®
 Product Code: 048-3

Application: Bio Ceramic Root Repair Material

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2. HAZARD IDENTIFICATION

Components used to manufacture TotalFill® Root Repair Material are not listed as carcinogens by NTP, OSHA or IARC. It may however contain trace amounts of substances recognized as carcinogens by these organizations.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Element		CAS #	ACGIH TLV	OSHA PEL	LD ₅₀
3CaO.SiO ₂	Tricalcium silicate	12168-85-3	10mg/m ³ total dust	5mg/m ³ respirable dust	N/A
2CaO.SiO ₂	Dicalcium silicate	10034-77-2		10mg/m ³ total dust	
ZrO ₂	Zirconium oxide	1314-23-4	5mg/m ³	5mg/m ³ TWA	N/A
Ta ₂ O ₅	Tantalum pentoxide	1314-61-0	5mg/m ³ total dust	5mg/m ³ total dust	Oral:>4000mg/kg Rat: 8000mg/kg
CaSO ₄ .1/2H ₂ O	Calcium sulphate (anhydrous)	7778-18-9	10mg/m ³ (TWA) inhalable fraction	15mg/m ³ total dust 5mg/m ³ respirable fraction	No LD ₅₀ /LC ₅₀

4. FIRST AID MEASURES

Eyes: Flush eyes thoroughly with water for at least 15 minutes. Seek medical aid.

Skin: Flush skin thoroughly with water and pH-neutral skin soap or a mild detergent for at least 15 minutes. Remove any contaminated clothes and shoes. Seek medical aid if irritation or inflammation develops.

Inhalation: Remove from exposure and move to fresh air immediately. Immediately seek medical aid if breathing is difficult, coughing persists or not breathing.

Ingestion: Do not induce vomiting. If conscious, have the victim drink plenty of water. Immediately seek medical aid.

5. FIRE FIGHTING MEASURES

Conditions of Flammability: Not determined
Auto-ignition Temp: 305 °C
Means of Extinction: Use water spray, dry chemical, carbon dioxide, or chemical foam.
Hazardous Combustion Products: None

Flash Point: None
Unusual Fire and Explosion Hazards: None
Upper Flammable Limit: None
Danger of Explosion: None
Lower Flammable Limit: None
Special Fire Fighting Procedures: None

6. ACCIDENTAL RELEASE MEASURES

Person-related safety precautions

Not required.

Measures for environmental protection

No special measures required.

Measures for cleaning of accidental release and spills

Wear appropriate personal protective equipment. Avoid contacting the paste (see Section 8). Use dry clean-up methods (moist paper towel) that do not disperse the paste into surface water or wash large amounts down drains and dispose of in a suitable container.

Additional information

No dangerous substances are released.

7. HANDLING AND STORAGE

Handling – Safe handling

This product is intended for use in dentistry only. Only adequately trained personnel should handle this product. Keep out of reach of children. Wear appropriate gloves to prevent skin exposure (PVC, PE, natural rubber or nitrile gloves).

Storage Requirements

Store at room temperature in a dry area. Store away from food and drinks. Store tightly closed in the packaging provided. Keep dry until used. Protect from excessive heat and cold. Do not store near ammonia, ammonia nitrate, chlorine or chlorine containing items.

Protection against explosions and fires

No special measures required.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Eyes: Wear safety glasses with side shields or goggles. Contact lenses should not be worn.
Hands: Wear gloves to prevent skin exposure.
Body: Lightweight protective clothing.
Respirators: Surgical masks are recommended.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state:	Solid (paste)	Flashpoint:	>150°C
Colour:	White	Evaporation Rate:	Not applicable
Odour:	No distinct odour	Vapour Pressure (at 20°C) (68°F):	Not applicable
Specific Gravity (H₂O=1.0):	Not determined	Vapour Density:	Not applicable
pH (in water):	>12 (Base)	Density:	Not determined
Boiling/Melting Point:	Not determined	Solubility in/Miscibility w/Water:	Slightly soluble

10. STABILITY AND REACTIVITY

Chemical stability

Product is stable. Keep dry until used.

Incompatibility

Product is alkaline. It is incompatible with acids, ammonia, ammonia nitrate, ammonium salts, aluminium metal and chlorine.

Reactivity conditions

No dangerous reactions known.

Hazardous Decomposition products

None under normal conditions of storage and use.

Hazardous Polymerisation

Will not occur.

Conditions to avoid

Avoid unintentional contact with water to prevent premature setting; contact will result in hydration and produces (caustic) calcium hydroxide.

11. TOXICOLOGY INFORMATION

Route of entry

Skin contact, eye contact, ingestion and inhalation.

Local effects

Irritation to skin, eyes, moist mucous membranes of the nose, throat and upper respiratory system.

Acute toxicity

Uncured material may cause irritation. Avoid contact with skin, mucous membranes and eyes. The material is contraindicated if a person is known to be allergic to any of the ingredients of the product.

Skin sensitisation

No allergic potential after multiple uses.

Mutagenicity

Non-mutagenic

Chronic toxicity

Uncured material: prolonged or frequently repeated skin contact may cause allergic skin reactions in some individuals. Immediate or delayed irritation or inflammation can occur in the eyes and skin. Delayed lung injury can occur.

12. ECOLOGICAL INFORMATION

No ecological problems to be anticipated if material is properly handled and used.

13. DISPOSAL CONSIDERATIONS

Dispose of waste material according to regional regulations. Dispose of packaging in an approved landfill or incinerator. Do not empty into drains.

14. TRANSPORT INFORMATION

No special precautions required. TotalFill® Root Repair Material is not classified for any mode of transportation.

15. REGULATORY INFORMATION

Safety Phrases:

S7/8 Store with the syringe cap tightly sealed on the syringe and sealed in the pouch.

Store with the jar lid tightly sealed on the jar and sealed in the pouch.
Store at room temperature.
Keep dry, avoid contact with moisture.

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S29 Do not empty into drains.

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

Risk phrase:

R41 Risk of serious damage to eyes.

16. FURTHER INFORMATION

The data given above covers exclusively the safety requirements of the product(s) and is based on our current knowledge and experience. It does not signify any warranty with regards to the products properties. This product is only supplied for specific uses in dentistry and must be used in accordance with the directions for use.