

**Safety Data Sheet of BCGP Pellet & 150 Series, TFGP(BC Pellet&150)-SDS**

Revised Date: November 01, 2019, Revision No. 1

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**Safety Data Sheet**

**1. Product and Company Details**

- Product Trade Name** : TOTALFILL Bioceramic Gutta Percha Pellet & 150 Series  
**Company name** : Sure Dent Corporation  
**address** : #809, 52, Sagimakgol-ro, Jungwon-gu,  
Seongnam-si, Gyeonggi-do, Korea  
Tel: +82-31-737-4720  
Fax: +82-31-737-4724  
E-mail: suredent@suredent.com, suredent@gmail.com
- Product type** : Dental filling material  
**Classification** : **CE/MDD - Class IIa** : 93/42/EEC + 2007/47/EC  
**US FDA – Class I** : Exemption 510K(Low-Risk Medical devices)  
**KFDA - Class II** : C10010.01  
**HC/CANADA - Class III**
- Intended use** : Used to fill a prepared root canal prior to tooth restoration.

**2. Composition/Ingredients**

Name	Weight (%)	Cas No.	EC No.	According to CLP
Gutta Percha	22 ~27	9003-31-0	-	-
Zinc Oxide	28~33	1314-13-2	215-222-5	Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Zirconium Oxide	26~31	1314-23-4	215-227-2	-
Barium Sulfate	8~13	7727-43-7	231-784-4	-
Coloring agent	0.01~0.2	-	-	-
Calcium Silicate Compound	0.02 ~ 0.06	12168-85-3 10034-77-2 12042-78-3	-	-
Others	-	-	-	-

**3. Hazard Identification**

3.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

Skin irritation (Category 2), H315

Eye irritation (Category 2), H319

3.2 Label elements

Labelling according Regulation (EC) No 1272/2008



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Signal word: Warning

Hazard Statements: H315 Causes skin irritation  
H319 Causes serious eye irritation.

**Precautionary Statements**

Prevention P280 Wear protective gloves/protective clothing/eye protection/face protection.  
Response P332+P313 If skin irritation occurs: Get medical advice/attention.  
P337+P313 If eye irritation persists: Get medical advice/attention.  
Storage P403+P235 Store in a well-ventilated place. Keep cool.  
P410 Protect from sunlight.  
Disposal P501 Dispose of contents/container according to the related regulations.

**4. First Aid Measures**

Consult a physician if allergic reaction requires attention.

**5. Fire Fighting Measures**

Extinguishing media - Water, carbon dioxide, dry chemical  
Fire fighting techniques - Firefighters should wear self-contained breathing apparatus, because thermal decomposition by products may present a health hazard.

**6. Handling and Storage**

No special precaution required.  
Store in a well-ventilated place. Keep cool.  
Avoid prolonged exposure to natural sunlight and direct heat.

**7. Exposure Control and Personal protection**

Respiratory protection – N/A  
Ventilation – N/A  
Protective gloves - A  
Eye protective – A  
Other protective clothing or equipment – A

**8. Physical and Chemical Properties**

Appearance – conical points	Explosion hazard – N/A
Specific gravity – 2.7g/cm <sup>3</sup>	Vapor pressure – N/A
Odor – No odor or taste	Melting point – 89 ~ 91 °C or 210°F
Color – Pink	Solubility in water – None
Vapor density – N/A	Boiling point – N/A

**9. Stability and Reactivity**

Stability – Stable

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Incompatibility (materials to avoid) – natural light, excessive heat and humidity

Hazardous polymerization – N/A

Hazardous decomposition or byproducts – N/A

**10. Toxicological information**

Inhalation – N/A ( considered a nuisance dust-avoid inhalation )

Eye contact – N/A (Causes serious eye irritation)

Skin contact – N/A (Causes skin irritation)

Ingestion – N/A ( not known to cause any significant health problem )

Carcinogenicity – NTP: N.A. IARC monographs: N.A. OSHA regulated: No

Mutagenicity – N/A

**11. Ecological information**

Environmental control measures – disposable only in accordance with prevailing health regulations

**12. Disposal consideration**

Dispose of contents/container according to the related regulations.

**13. Transport information**

13.1. UN number: N/A

13.2. UN proper shipping name: N/A

13.3. Transport hazard class(es) : N/A

13.4. Packing group : N/A

13.5. Environmental hazards : N/A

13.6. Special precautions for user : N/A

13.7. Transport in bulk according to Annex II of Marpol and the IBC Code : N/A

**14. Regulatory information/Labeling international regulations**

14.1 Safety, health and environmental regulations/legislation specific for the substance or mixture  
This safety datasheet complies with the requirements of Regulation (EC) No 1272/2008.

14.2 Other regulations according to domestic and foreign laws

Follow the regulations of the Directive 93/42/EEC and 2007/42/EC (EU)

Follow the regulations of Exemption Premarket Notification 510(k) (21 CFR 862-892) (FDA)

Follow the regulations of the Korea Food & Drug Administration (KOREA)

Follow the regulations SOR/98-282 (CANADA)

**15. Other information**

This SDS has been created on the basis of the components safety data sheets. The employer is obliged to inform all employees, who have contact with any hazards, about risks and personal protective equipment specified in that Safety Data Sheet.