

Safety Data Sheet

1. Product and Company Details

Product Trade Name : TOTALFILL Bioceramic Gutta Percha Pellet & 150 Series
Company name : Sure Dent Corporation
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Seongnam-si, Gyeonggi-do, Korea
Tel: +82-31-737-4720
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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



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/cm³ Vapor pressure – N/A

Odor – No odor or taste Melting point – 79 ~ 84°C

Color – Pink Solubility in water – None

Vapor density – N/A Boiling point – N/A

9. Stability and Reactivity

Stability – Stable

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.