

Safety Data Sheet

1. Identification of substance or mixture and company

1.1 Product identifier

Trade name : TOTALFILL Bioceramic Gutta Percha Pellet & 150 Series

1.2 Application of the substance / the mixture

Dental Filling Material used to fill a prepared root canal prior to tooth restoration.

For Dental Use Only

1.3 Details of the supplier of the safety data sheet

Manufacturer : Sure Dent Corporation
#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

1.4 Emergency telephone number : +82-31-737-4720

2. Hazards Identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

None

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

The product is classified and labeled according to the CLP regulation.

Hazard pictograms



Signal word: Warning

Hazard-determining components of labeling:

Zinc Oxide

Hazard Statements: H400: Very toxic to aquatic life

H401: Toxic to aquatic life

Precautionary Statements

Prevention P280 Wear protective gloves/protective clothing/eye protection/face protection.
P235+410: Keep cool. Protect from sunlight.

Storage P410 Protect from sunlight.

Disposal P501 Dispose of contents/container according to the related regulations.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.
vPvB: Not applicable.

3. Composition/information on ingredients

3.1 Chemical characterization: Mixture

Description: Mixture of substances listed below with nonhazardous additions.

Dangerous components:			
Zinc Oxide	CAS No. 1314-13-2 EC No. 215-222-5	Aquatic Acute 1, H400 Aquatic Chronic 1, H410	28-33%

4. First-aid Measures

4.1 Description of first-aid measures

After inhalation : Remove with fresh air.
After skin contact : Flush with lots of water.
After eye contact : Wash exposed area with lots of running water.
After ingestion : Seek immediate medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms

No particular reactions of the human body to the product known up till now.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment

Symptomatic treatment.

5. Firefighting Measures

5.1 Extinguishing media

Suitable extinguishing media: Water, carbon dioxide, dry chemical

Unsuitable extinguishing media: There is no restriction on the type of extinguisher.

5.2 Special hazards arising from the substance or mixture: No further relevant information available.

5.3 Advice for firefighters

Protective equipment:

Firefighters should wear self-contained breathing apparatus, because thermal decomposition by products may present a health hazard.

6. Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

6.2 Environmental precautions

No special measures required.

6.3 Methods and material for containment and cleaning up

For small amounts: Take up product using suitable devices and dispose of.

For large amounts: Take up product using suitable devices and dispose of.

6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7. Handling and Storage

7.1 Precautions for safe handling

Handling

No special precaution required.

Fire and explosion protection

Take precautionary measures against static discharges.

Keep away from any source of ignition

7.2 Conditions for safe storage, including any incompatibilities

Storage : Protect from sunlight.

Keep cool

Storage stability : Store in a cool area and avoid exposure to direct sunlight.

7.3 Specific end use(s): Dental Filling Material used to fill a prepared root canal prior to tooth restoration.

8. Exposure Controls/personal protection

8.1 Control parameters

Components with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

Additional information: The lists that were valid during the creation were used as basis.

8.2 Exposure controls

Personal protection equipment

General protective and hygienic measures: No particular measures necessary

Respiratory protection: No particular measures necessary

Protection of hands: Protective gloves

· Material of gloves

The selection of suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

The exact breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection: Safety glasses with side shield.

Body protection: Protective work clothing

9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Appearance

Form

Conical points

Color

Pink

Odor

No odor or taste

pH

Not applicable

Melting point

79 ~ 84°C

Boiling point/Boiling range

Not applicable

Flash point	Not applicable
Evaporation rate	Not applicable
Flammability(solid,gas)	Not applicable
Ignition temperature	Not applicable
Vapour pressure	Not applicable
Vapor density	Not applicable
Relative density	Not applicable
Solubility in water	Not soluble
Partition coefficient (n-octano/water)	Not applicable
Viscosity	Not applicable
Explosive properties	Not applicable
Oxidizing properties	Not applicable

9.2 Other information

No further relevant information available.

10. Stability and Reactivity

10.1 Reactivity

This material is considered to be non reactive under normal use conditions.

10.2 Chemical stability

Stable under normal condition of storage and use.

10.3 Possibility of hazardous reactions

No dangerous reaction known.

10.4 Conditions to avoid

No further relevant information available.

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous decomposition products

No hazardous decomposition products known.

11. Toxicological information

Acute toxicity

Not toxic

Skin corrosion/ irritation

Not toxic

Serious eye damage/ irritation

Not toxic

Respiratory or skin sensitization

No data available

Germ cell mutagenicity

No data available

Carcinogenicity

N.A. IARC monographs: Not applicable

OSHA regulated: Not applicable

Reproductive toxicity

No data available

Specific target organ toxicity (single exposure)

No data available

Specific target organ toxicity (repeated exposure)

No data available

Aspiration hazard

No data available

Additional information regarding toxicity

In our experience and according to our knowledge the product has no hazardous effects if handled properly and used for the purpose intended.

12. Ecological information

12.1 Toxicity

May cause acute and chronic toxicity according to CLP regulation.

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Other adverse effects

No data available

13. Disposal consideration

13.1 Waste treatment methods

- **Recommendation:** Dispose of contents/container according to the related regulations.
- **Uncleaned packaging:** Disposal must be made according to official regulations.
- **Additional information:** No further relevant information available.

14. Transport information

14.1. UN number: Not Applicable

14.2. UN proper shipping name: Not Applicable

14.3. Transport hazard class(es) : Not Applicable

14.4. Packing group : Not Applicable

14.5. Environmental hazards : Not Applicable

14.6. Special precautions for user : Not Applicable

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code : Not Applicable

15. Regulatory information/Labeling international regulations

15.1 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.

15.2 Chemical Safety Assessment

Chemical safety assessment has not been carried out.

15.3 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) (US FDA)

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

Follow the regulations SOR/98-282 (CANADA)

Follow the regulations TG (MD) R & TG Act (AUSTRALIA)

Follow the regulations MHLW Ministerial Ordinance No. 169 & PMD Act (JAPAN)

16. 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.