SAFETY DATA SHEET
according to Regulation (EC) No. 453/2010
Dental Use

Genius™ Gutta Percha

SECTION 1 : Identification of the substance/preparation and of the company/undertaking

1.1. Product identifier
Product code : 4294 - 4299
Product name : Genius™ Gutta Percha
Product description : Dental root canal filling material

1.2. Relevant identified uses of the substance or mixture and uses advised against
Relevant identified uses : Professional Dental Root Canal Filling Material

1.3. Details of the supplier of the safety data sheet
Manufacturer
Ultradent Products, Inc.
505 W. 10200 S.
South Jordan, UT 84095

Distributor
Ultradent Products GmbH
Am Westhover Berg 30
51149 Cologne Germany
Email: infoDE@ultradent.com
Emergency Phone : +49(0)2203-35-92-0

1.4. Emergency telephone number
CHEMTREC (NORTH AMERICA) : (800) 424 - 9300
(International) : +1(703) 527 - 3887

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture
Classification according to Regulation(EC) No 1272/2008 [CLP]
Environmental : Acute Hazards to the Aquatic Environment, Acute Category 1
Chronic Hazards to the Aquatic Environment, Chronic Category 1

2.2. Label elements
Classification according to Regulation(EC) No 1272/2008 [CLP]
Hazard pictogram(s) :

Signal Word : WARNING
Hazard statement(s) : H410: Very toxic to aquatic life with long lasting effects.
Precautionary statement(s)
Response : P305: IF IN EYES:
P351: Rinse cautiously with water for several minutes.
P337+P313: If eye irritation persists: Get medical advice/attention.
P301: IF SWALLOWED:
P314: Get medical advice/attention if you feel unwell.
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Storage: P233: Keep container tightly closed.
P235: Keep cool.


2.3. Other hazards
Immediate concerns: Harmful to aquatic life with long lasting effects.

SECTION 3: Composition / Information on ingredients

3.1. Substances
Not Applicable

3.2. Mixtures

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS</th>
<th>EINECS No.</th>
<th>Wt.%</th>
<th>Classification according to Regulation(EC) No 1272/2008 [CLP]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zinc Oxide</td>
<td>1314-13-2</td>
<td>215-222-5</td>
<td>&lt; 50</td>
<td>Aquatic Acute, Cat. 1; H410; H400</td>
</tr>
</tbody>
</table>

For full text of H-statements: see SECTION 16.

SECTION 4: First aid measures

4.1. Description of first aid measures
Following eyes: Flush eyes with water. Get medical attention if irritation develops or persists.
Following skin: The specific indications will not cause irritation
Following ingestion: If swallowed in small quantity the product is harmless, otherwise consult a doctor.
Following inhalation: No specific treatment is necessary since this material is not likely to be hazardous by inhalation.

4.2. Most important symptoms and effects, both acute and delayed
Eyes: May be mildly irritating to eyes.
Skin: Non-irritating to the skin.
Ingestion: May be harmful if swallowed in large quantities.
Inhalation: None expected for this product.

4.3. Indication of any immediate medical attention and special treatment needed
Notes to physician: Not applicable.

SECTION 5: Fire fighting measures

5.1. Extinguishing media
Extinguishing media: Water spray, Extinguishing powder, sand, foam, Carbon Dioxide (CO2)

5.2. Special hazards arising from the substance or mixture
Hazardous combustion products: None known.

5.3. Advice for firefighters
Fire fighting procedures: As in any fire, wear self-contained breathing apparatus pressure demand, (MSHA/NIOSH) approved or equivalent) and full protective gear.
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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Special protective equipment: Wear suitable protective clothing, gloves and eye/face protection.

6.2. Environmental precautions

Water spill: Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Small spill: Wipe up and discard in a suitable container.
Large spill: Shovel or vacuum spill and place in a container for disposal.

6.4. Reference to other sections

Reference to other sections: Not Applicable

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handling: Keep away from heat sources and direct sunlight.
Storage: Keep container tightly closed in a cool place.

7.2. Conditions for safe storage, including any incompatibilities

Storage temperature: See product labeling

7.3. Specific end use(s)

Specific end use(s): Professional Dental Root Canal Filling Material

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters: Zinc oxide: PEL/TLV: 5 mg/m³ (zinc fume)

8.2. Exposure controls

Eye/face protection: Use chemical splash goggles.
Skin protection: Wear suitable protective clothing and gloves.
Respiratory protection: No special measures required.
Work hygienic practices: Use normal care when working with chemicals.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: Solid
Appearance: Uniformly cylindrical shape
Colour: Pink
Melting temperature: 100 deg C
Boiling temperature: Not Applicable
Flash point: None
Flammability (solid, gas): Not Applicable
Vapor pressure: Not Applicable
### GENIUS™ GUTTA PERCHA

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vapor density</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Specific gravity</td>
<td>2.7</td>
</tr>
<tr>
<td>Solubility in water</td>
<td>None</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

### 9.2. Other information

| Additional information           | Not Applicable         |

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

**Reactivity**: Stable

#### 10.2. Chemical stability

**Chemical stability**: Stable when stored and handled under recommended conditions.

#### 10.3. Possibility of hazardous reactions

**Hazardous polymerization**: Will not occur.

#### 10.4. Conditions to avoid

**Conditions to avoid**: Natural light, excessive heat and humidity (stability)

#### 10.5. Incompatible materials

**Incompatible materials**: Strong oxidizing agents

#### 10.6. Hazardous decomposition products

**Hazardous decomposition products**: Carbon monoxide, carbon dioxide, hydrocarbon, and zinc. Fumes when heated to decomposition.

### SECTION 11: Toxicological information

#### 11.1. Information on toxicological effects

**Acute Notes**: Device is biocompatible when used as directed by dental professionals per ISO 10993-1.

### SECTION 12: Ecological information

#### 12.1. Toxicity

**Aquatic toxicity (acute)**: Do not allow to enter sewers or drains that may lead to waterways.

#### 12.2. Persistence and degradability

**Persistence and degradability**: Not Determined

#### 12.3. Bioaccumulative potential

**Bioaccumulative potential**: Not Determined

#### 12.4. Mobility in soil

**Mobility in soil**: Not Determined

#### 12.5. Results of PBT and vPvB assessment

**Results of PBT and vPvB assessment**: Not Determined

#### 12.6. Other adverse effects
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Date Issued : 01/19/2016
SDS No : 383-001.1

Environmental data : Do not flush to sewer.

SECTION 13: Disposal considerations

13.1. Waste treatment methods


SECTION 14: Transport information

14.1. UN number

UN number : N/A

14.2. UN proper shipping name

UN proper shipping name : Not Dangerous Goods

14.3. Transport hazard class(es)

Hazard classification : N/A

14.4. Packing group

Packing group : N/A

14.5. Environmental hazards

Marine pollutant #1 : Not Dangerous Goods

14.6. Special precautions for user

ADR - road : Not Dangerous Goods
RID - rail : Not Dangerous Goods
IMDG - sea : Not Dangerous Goods
IATA - air : Not Dangerous Goods

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Transport in bulk : Not Dangerous Goods

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

RoHS : Please refer to Medical Devices Directive 93/42/EEC

15.2. Chemical safety assessment

Chemical safety assessment : See Section 11
Additional information : This product is not considered dangerous for transportation

SECTION 16: Other information

Relevant H-statements (number and full text) : Aquatic Acute, Cat. 1: Acute Hazards to the Aquatic Environment, Category 1
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.

Prepared by : Corey Jaseph
General statements : N/A = Not Applicable
Additional SDS information : This is the first SDS.
Manufacturer disclaimer : FOR DENTAL USE ONLY: Use as directed. The information and
Genius™ Gutta Percha

recommendations are taken from sources (raw material SDS(s) and manufacturer's knowledge) believed to be accurate; however, the manufacturer, makes no warranty with respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof. Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.