

# SAFETY DATA SHEET

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

**ULTRADENT**  
PRODUCTS, INC.

Date Issued : 01/19/2016  
SDS No : 383-001.1

## 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]

: The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

**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)** :   
Environment

**Signal Word** : WARNING

**Hazard statement(s)** : H410: Very toxic to aquatic life with long lasting effects.

##### Precautionary statement(s)

**Prevention** : P280: Wear protective gloves/protective clothing/eye protection/face protection.

**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.

**Disposal** : P501: Dispose of in compliance with governmental regulations (EC 1975L0442-20/11/2003).

### 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

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

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/m<sup>3</sup> (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

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Vapor density : Not Applicable  
 Specific gravity : 2.7  
 Solubility in water : None  
 Auto-ignition temperature : Not Applicable

**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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Environmental data : Do not flush to sewer.

**SECTION 13: Disposal considerations**

**13.1. Waste treatment methods**

Disposal method : Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

**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

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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.