

## Safety Data Sheet

Safety Data Sheet (conforms to with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 2015/830), US 29CFR1910.1200, Canada Hazardous Products Regulation

Date Issued: 31 August 2016  
Document Number: 605  
Date Revised: 28 December 2017  
Revision Number: 2

### 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

#### 1.1 Product Identifier:

**Trade Name (as labeled):** Celtra® Ceram Powder Porcelains: Dentin, Opaque Dentin, Natural Enamel, Opal Enamel, Power Dentin, Dentin Gingiva, Dentin Effect, Enamel Effect, Add-on Correction, Add-on Gingiva, Universal Overglaze

**Part/Item Number:** 615130-615149, 615150-615156, 650130-650149, 615700-615725, 650700-650725; 615201-615205, 650201-650206; 615211-615216, 650211-650216; 615181-615186, 650181-650186; 615171-615175, 650171-650175; 615161-615169, 650161-650168; 615221-615226; 650221-650226; 615401-615404, 650401-650404; 615411-615415, 650411-650415; 615540, 605540

#### 1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against:

**Recommended Use:** Used in the fabrication of dental crowns and bridges.  
**Restrictions on Use:** For Professional Use Only

#### 1.3 Details of the Supplier of the Safety Data Sheet:

**Manufacturer/Supplier Name:** Dentsply Sirona Prosthetics  
**Manufacturer/Supplier Address:** 570 West College Ave.  
York, PA 17401  
**Manufacturer/Supplier Telephone Number:** 717-845-7511 (Product Information)  
**Email address:** [Prosthetics\\_MSDS@Dentsplysirona.com](mailto:Prosthetics_MSDS@Dentsplysirona.com)

#### 1.4 Emergency Telephone Number:

**Emergency Contact Telephone Number:** 800-243-1942

### 2. HAZARDS IDENTIFICATION

#### 2.1 Classification of the Substance or Mixture:

GHS Classification:		
Health	Environmental	Physical
Not Hazardous	Not Hazardous	Not Hazardous

#### 2.2 Label Elements:

Not Required

**Signal Word:** None

<b>Hazard Phrases</b>	<b>Precautionary Phrases</b>
None Required	None Required

**2.3 Other Hazards:** None known.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.2 Mixture:

<b>Hazardous Components</b>	<b>C.A.S. #</b>	<b>EINECS # / REACH Registration #</b>	<b>Classification</b>	<b>WT %</b>
Crystalline Silica (Quartz)	14808-60-7	238-878-4 /	STOT RE 1 (H372) Carc. 1 (H350)	55-65
Aluminum Oxide	1344-28-1	215-691-6 /	Not applicable	10-15
Sodium Oxide	1313-59-3	215-208-9 /	Skin Corr. 1B, H314	5-10
Non-Hazardous Ingredients	Not Applicable	Not Applicable	Not Applicable	1-15
Boron Trioxide	1303-86-2	215-125-8 /	Repro 1B, H360	1-10
Barium Oxide	1304-28-5	215-127-9 /	Oxid. Sol. 1, H271 Acute Tox. 3, H301 Eye Dam. 1, H318 Skin Corr. 1B, H314	1-5
Lithium oxide	12057-24-8	235-019-5 /	Eye Dam. 1, H318 Skin Corr. 1B, H314	<3
Diterbium Trioxide	12036-41-8	234-849-5 /	Eye Irr. 2, H319, Skin Irr. 2, H315 STOT SE 3, H335	<3
Calcium Oxide	1305-78-8	215-138-9 /	Eye Dam. 1, H318 Skin Irr. 2, H315 STOT SE 3, H335	<2
Antimony Trioxide	1309-64-4	215-175-0 /	Carc. 2, H351 Repr. 1A, H360D STOT RE 2, H373	<1
Titanium Dioxide	13463-67-7	236-675-5 /	Carc. 2, H351	<1
Diphosphorus Pentaoxide	1314-56-3	215-236-1 /	Eye Dam. 1, H318 Skin Corr. 1A, H314	<1
Fluorine	7782-41-4	231-954-8 /	Eye Dam. 1, H318 Skin Corr. 1A, H314 Acute Tox 1, H310 Acute Tox 2, H300, H330	<1

Note: The components in this product are inextricably bound together within the glass matrix of this product. The dust produced during the handling of the porcelain powders is not hazardous.

**The exact concentration is being withheld as a trade secret.**

**Refer to Section 16 for the full text of the GHS Classifications.**

### 4. FIRST AID MEASURES

<b>4.1 Description of First Aid Measures:</b>	
<b>Eye</b>	Do not rub your eyes. Product powder may cause abrasive eye injury. Flush eyes thoroughly with water, holding open eyelids. Get medical attention if irritation persists.
<b>Skin</b>	Do not rub or scratch. Product powder may cause mechanical irritation. Wash exposed skin with soap and water. If skin irritation persists, get medical attention. Launder contaminated clothing before reuse.
<b>Inhalation</b>	If irritation develops, remove victim to fresh air.
<b>Ingestion</b>	May cause gastrointestinal effects. Seek medical attention if large amounts are swallowed.
<b>4.2 Most Important Symptoms and Effects, Both Acute and Delayed:</b>	
This product is a non-hazardous, fine porcelain powder. Exposures during use; or the polishing or grinding of solid material may cause mechanical irritation to eyes, skin, or respiratory tract.	
<b>4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:</b>	
Immediate medical attention is not required.	

## 5. FIRE-FIGHTING MEASURES

<b>5.1 Extinguishing Media:</b>	Use media appropriate for surrounding fire.
<b>5.2 Special Hazards Arising from the Substance or Mixture:</b>	
None known.	
<b>5.3 Advice for Fire-Fighters:</b>	
<b>Fire Fighting Procedures/Precautions for Fire Fighters:</b>	Use water to cool fire exposed containers and structures. Firefighters should wear full emergency equipment and approved positive pressure self-contained breathing apparatus.

## 6. ACCIDENTAL RELEASE MEASURES

<b>6.1 Personal Precautions, Protective Equipment and Emergency Procedures:</b>	
If exposed to product spills; or the dust from grinding and polishing of solid product, wear appropriate protective clothing as described in Section 8. Avoid contact with eyes. Avoid breathing product dust.	
<b>6.2 Environmental Precautions:</b>	
Report releases as required by local and national authorities.	
<b>6.3 Methods and Material for Containment and Cleaning up:</b>	
For product spills; or the dust from grinding or polishing of solid products: Contain spills, sweep or gather spilled material in a manner that minimizes the generation of airborne dusts, and transfer to a suitable container for disposal. Pick up solid product and transfer to a suitable container for disposal.	
<b>6.4 Reference to Other Sections:</b>	
Refer to Section 8 for Personal Protective Equipment and Section 13 for Disposal information.	

## 7. HANDLING AND STORAGE

<b>7.1 Precautions for Safe Handling:</b>
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Avoid generating dust through processing and handling. Avoid breathing product dusts. Use adequate ventilation for polishing or grinding operations. Wash hands thoroughly after polishing or grinding teeth. Use good housekeeping to minimize accumulation of dust.

Empty containers retain product residues and can be hazardous. Follow all SDS precautions when handling empty containers.

**7.2 Conditions for Safe Storage, Including Any Incompatibilities:** Store in a tightly closed container in a cool, well-ventilated location away from incompatible materials. Store away from food or beverages.

**7.3 Specific End Use (s):** For professional use only.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control Parameters:

#### Occupational Exposure Limits:

Crystalline Silica Quartz	0.05 mg/m <sup>3</sup> TWA OSHA PEL (Respirable dust) <sup>1</sup>  10 mg/m <sup>3</sup> TWA OSHA PEL (Respirable fraction) % SiO <sub>2</sub> + 2 30 mg/m <sup>3</sup> TWA OSHA PEL (Total dust) % SiO <sub>2</sub> + 2 0.025 mg/m <sup>3</sup> TWA ACGIH TLV (Respirable) 0.1 mg/m <sup>3</sup> TWA UK WEL ( as Silica, respirable crystalline) Belgium: 0.1 mg/m <sup>3</sup> TWA
Aluminum Oxide	5 mg/m <sup>3</sup> (respirable fraction), 15 mg/m <sup>3</sup> (total dust) TWA OSHA PEL 1 mg/m <sup>3</sup> TWA ACGIH TLV (Respirable) (as Aluminum, metal and insoluble compounds) 4 mg/m <sup>3</sup> TWA DFG MAK (Inhalable) 1.5 mg/m <sup>3</sup> TWA DFG MAK (Respirable) 10 mg/m <sup>3</sup> (Inhalable) TWA UK WEL 4 mg/m <sup>3</sup> (Respirable) TWA UK WEL
Sodium Oxide	None Established
Non-Hazardous Ingredients	None Established
Boron Trioxide	10 mg/m <sup>3</sup> ACGIH TLV 15 mg/m <sup>3</sup> OSHA PEL (total dust) 10 mg/m <sup>3</sup> TWA, 20 mg/m <sup>3</sup> STEL UK WEL 10 mg/m <sup>3</sup> TWA Belgium OEL
Barium Oxide	None Established
Lithium Oxide	1 mg/m <sup>3</sup> Ceiling AIHA WEEL
Diterbium Trioxide	None Established
Calcium Oxide	2 mg/m <sup>3</sup> TWA ACGIH TLV 5 mg/m <sup>3</sup> TWA OSHA PEL 1 mg/m <sup>3</sup> TWA, 2 mg/m <sup>3</sup> STEL DFG MAK (Inhalable) 2 mg/m <sup>3</sup> TWA UK WEL 2 mg/m <sup>3</sup> TWA Belgium OEL

Antimony Trioxide	0.5 mg/m <sup>3</sup> TWA ACGIH TLV 0.5 mg/m <sup>3</sup> TWA OSHA PEL 0.5 mg/m <sup>3</sup> TWA UK WEL
Titanium Dioxide	10 mg/m <sup>3</sup> TWA ACGIH TLV 15 mg/m <sup>3</sup> TWA (Total dust) OSHA PEL 10 mg/m <sup>3</sup> (Inhalable) TWA UK WEL 4 mg/m <sup>3</sup> (Respirable) TWA UK WEL 10 mg/m <sup>3</sup> TWA Belgium OEL
Diphosphorus pentaoxide	2 mg/m <sup>3</sup> TWA, 4 mg/m <sup>3</sup> STEL DFG MAK (Inhalable) 1 mg/m <sup>3</sup> TWA, 2 mg/m <sup>3</sup> STEL UK WEL 1 mg/m <sup>3</sup> TWA, Belgium OEL
Fluorine	1 ppm TWA, 2 ppm STEL ACGIH TLV 0.1 ppm TWA OSHA PEL 1 ppm TWA, 2 ppm STEL DFG MAK 1 ppm STEL UK WEL 1 ppm TWA, 2 ppm STEL Belgium OEL

<sup>1</sup> 1910.1053 2016 OSHA PEL effective June 23, 2018

**Note: The components of this product are inextricably bound together within the glass matrix of this product and pose no risk of exposure during processing or handling.**

<b>Biological Exposure Limits:</b> None Established
<b>8.2 Exposure Controls:</b>
<b>Appropriate Engineering Controls:</b> Use ventilation that is adequate to keep employee exposure to airborne concentrations below exposure limits.
<b>Individual Protection Measures (PPE):</b> <b>Specific Eye/face Protection:</b> Follow facility requirements for operation. <b>Specific Skin Protection:</b> None required during the normal use of this product. <b>Specific Respiratory Protection:</b> If needed, an approved respirator with high efficiency particulate filters may be used. For higher exposures, a supplied air respirator may be required. Respirator selection and use should be based on contaminant type, form and concentration. Follow applicable regulations and good Industrial Hygiene practice. <b>Specific Thermal Hazards:</b> None required

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on Basic Physical and Chemical Properties:

<b>Appearance:</b>	White or colored powder	<b>Explosive limits:</b>	<b>LEL:</b> Not applicable <b>UEL:</b> Not applicable
<b>Odor:</b>	Odorless	<b>Vapor pressure (mmHg):</b>	Not applicable
<b>Odor threshold:</b>	Not applicable	<b>Vapor density:</b>	Not applicable
<b>pH:</b>	Not applicable	<b>Relative density:</b>	Not available
<b>Melting/freezing point:</b>	Not available	<b>Solubility(ies):</b>	In water: Insoluble

<b>Initial boiling point and boiling range:</b>	Not applicable	<b>Partition coefficient: n-octanol/water:</b>	Not applicable
<b>Flash point:</b>	Not applicable	<b>Auto-ignition temperature:</b>	Not applicable
<b>Evaporation rate:</b>	Not applicable	<b>Decomposition temperature:</b>	Not available
<b>Flammability (solid, gas):</b>	Not flammable	<b>Viscosity:</b>	Not applicable
<b>Explosive Properties:</b>	Not explosive	<b>Oxidizing Properties:</b>	None

**9.2 Other Information:** None available

## 10. STABILITY AND REACTIVITY

<b>10.1 Reactivity:</b> Non-reactive
<b>10.2 Chemical Stability:</b> Stable under normal conditions.
<b>10.3 Possibility of Hazardous Reactions:</b> Hazardous polymerization will not occur.
<b>10.4 Conditions to Avoid:</b> None known.
<b>10.5 Incompatible materials:</b> Avoid oxidizing agents, strong acids, strong bases, ethylene oxide, halogenated hydrocarbon, and chlorine trifluoride.
<b>10.6 Hazardous Decomposition Products:</b> Irritating fumes and oxides may be released when product is heated.

## 11. TOXICOLOGICAL INFORMATION

### 11.1 Information on Toxicological Effects:

<b>Potential Health Effects:</b> <u>Eyes:</u> Not classified as an eye irritant, but mechanical irritation may occur. <u>Skin:</u> Not classified as a skin irritant, but mechanical irritation may occur. <u>Ingestion:</u> May cause gastrointestinal effects. <u>Inhalation:</u> Product dusts may cause mild respiratory irritation.
<b>Chronic Health Effects:</b> None expected.
<b>Irritation:</b> This product is not expected to cause eye or skin irritation. Mechanical irritation may occur.
<b>Corrosivity:</b> No data available. This product is not expected to be corrosive.
<b>Sensitization:</b> No adverse effects expected. Components are not sensitizers.
<b>Carcinogenicity:</b> Crystalline silica quartz is listed as "Carcinogenic to Humans" (Group 1) by IARC and "Known to be a Human Carcinogen" by NTP. Antimony Trioxide is listed as "Possibly Carcinogenic to Humans" (Group 2B) by IARC. Titanium Dioxide is classified by IARC as a group 2B carcinogen (possible human carcinogen). The components of this product are inextricably bound together during the glass melting/forming process during manufacturing. Therefore, there is no exposure to Antimony Trioxide, Crystalline silica, or Titanium dioxide during the normal use and handling. None of the other components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH, or the EU CLP.

**Mutagenicity:** No data available. This product is not expected to cause mutagenicity activity.

**Acute Toxicity Data:**

Crystalline Silica: Oral Rat LD50 - >22,500 mg/kg.

Aluminum Oxide: Oral rat LD50->10000 mg/kg, Inhalation rat LC50- 7.6 mg/L/hr.

Sodium Oxide: No toxicity data available

Non-Hazardous Ingredients: Not acutely toxic.

Boron Trioxide: Oral rat LD50- 3450 mg/mg, Inhalation rat LC50- >2.12 mg/L/hr. (no deaths), Skin rabbit LD50- >2000 mg/kg

Barium Oxide: No toxicity data available

Lithium Oxide: No toxicity data available

Diterbium Trioxide: No toxicity data available

Calcium Oxide: Oral rat LD50->2000 mg/kg, Skin rabbit LD50->2500 mg/kg

Antimony Trioxide: Inhalation rat LC50- >5.2 mg/L/hr., Skin rabbit LD50- >8300 mg/kg

Tin Dioxide: Inhalation rat LC50- >2.04 mg/L/hr. (no deaths)

Titanium Dioxide: Oral rat LD50 >5000 mg/kg, Inhalation rat LC50 >6.82 mg/L/4 hr.

Zirconium Dioxide: Oral rat LD50->5000 mg/kg; Inhalation rat LC50->4.3 mg/L/hr.

Diphosphorus pentaoxide: Inhalation rat LC50- 0.304 mg/L/hr.

**Reproductive Toxicity Data: Boron Oxide:** In an animal study, rats exposed to the high dose of 336 mg/kg by weight boric acid (corresponding to a level of 58.5 mg Boron/kg bw) were sterile. Microscopic examination of the atrophied testes of all males in this group showed no viable sperm. There were also reported evidence of decreased ovulation in about half of the ovaries examined from the females exposed to 58.5 mg Boron/kg bw and only 1/16 mating produced a litter from these high dose females when mated with control male animals. In another animal study, an increased incidence of malformed live fetuses/litter was observed at 43.5 mg Boron/kg by weight, primarily due to cardiovascular defects.

**Antimony trioxide:** Pregnant female rats (six to seven per group) were exposed by inhalation to 0, 0.027, 0.082 or 0.27 mg/m<sup>3</sup> antimony trioxide for 24 hours per day for 21 days. Fetal growth and viability were assessed at the end of gestation. Maternal body weight gain was not affected by exposure, but, at the high-dose level, increased pre- and post-implantation death of embryos was observed. At the mid-dose level, preimplantation loss and fetal growth retardation were evident. The Boron oxide and Antimony trioxide in this product are bound in a glass matrix, exposure is unlikely.

**Specific Target Organ Toxicity Single Exposure (STOT-SE):** No data available.

**Specific Target Organ Toxicity Repeated Exposure (STOT-RE):** No data available.

## 12. ECOLOGICAL INFORMATION

**12.1 Toxicity:**

This product is not expected to present an environmental hazard.

**12.2 Persistence and Degradability:** Biodegradation is not applicable to inorganic substances.

**12.3 Bio-accumulative Potential:** No data is currently available.

**12.4 Mobility in Soil:** No data is currently available.

**12.5 Results of PBT and vPvB Assessment:** Not required.

**12.6 Other Adverse Effects:** None known.

### 13. DISPOSAL CONSIDERATIONS

#### 13.1 Waste Treatment Methods:

**Waste Treatment Recommendations:** Dispose in accordance with all national and local regulations. Avoid generating airborne dust.

### 14. TRANSPORT INFORMATION

	14.1 UN Number	14.2 UN Proper Shipping Name	14.3 Hazard Class(s)	14.4 Packing Group	14.5 Environmental Hazards
<b>DOT</b>	None	Not Regulated	None	None	Not applicable
<b>ADR/RID</b>	None	Not Regulated	None	None	Not applicable
<b>IMDG</b>	None	Not Regulated	None	None	Not applicable
<b>IATA/ICAO</b>	None	Not Regulated	None	None	Not applicable

**14.6 Special Precautions for User:** Not applicable.

**14.7 Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code:** Not applicable.

### 15. REGULATORY INFORMATION

#### 15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture:

##### U.S. Federal Regulations

**Comprehensive Environmental Response and Liability Act of 1980 (CERCLA):** This product has a Reportable Quantity (RQ) of 100,000 lbs. (based on the RQ for Antimony Trioxide of 1,000 lbs. listed at <1%). Releases above the RQ must be reported to the National Response Center. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.

**Toxic Substances Control Act (TSCA):** All of the components of this product are listed on the TSCA inventory.

**Clean Water Act (CWA):** This material is not regulated under the Clean Water Act.

**Clean Air Act (CAA):** Antimony trioxide (as antimony compounds) is regulated under the Clean Air Act.

##### **Superfund Amendments and Reauthorization Act (SARA) Title III Information:**

**SARA Section 311/312 (40 CFR 370) Hazard Categories:** Not Hazardous.

**This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):** None.

##### State Regulations

**California:** This product contains the following substances known to the state of California to cause cancer and/or reproductive toxicity: Crystalline Silica (55-65%), Titanium dioxide (<1%), and Antimony Trioxide (<1%).

\*Note: The Crystalline Silica, Titanium dioxide, and Antimony Trioxide in this product are bound within the glass matrix and no exposure should occur.

##### International Regulations

**Canadian Environmental Protection Act:** All of the components in this product are listed on the Domestic Substances

list (DSL).

**European Inventory of Existing Chemicals (EINECS):** All of the components in this product are listed on the EINECS inventory.

**EU REACH:** All components requiring registration have been pre-registered.

**Australian Inventory of Chemical Substances:** All of the components in this product are listed on the AICS for Australia.

**Japanese Existing and New Chemical Substances:** All of the components in this product are listed on the Japanese ENCS list.

**China Inventory of Existing Chemicals and Chemical Substances:** All of the components in this product are listed on the IECSC for China.

**Philippine Inventory of Chemicals and Chemical Substances:** All of the other components in this product are listed on the PICCS.

**Korean Existing Chemicals List:** All of the components in this product are listed on the KECL for Korea.

**15.2 Chemical Safety Assessment:** None required.

## 16. OTHER INFORMATION

HMIS Hazard Rating:

Health – 1      Flammability – 0      Physical Hazard – 0

Full text of Classification abbreviations used in Section 2 and 3:

Acute Tox. 1 Acute Toxicity Category 1

Acute Tox. 2 Acute Toxicity Category 2

Acute Tox. 3 Acute Toxicity Category 3

Carc. 1 Carcinogen Category 1

Carc. 2 Carcinogen Category 2

Eye Dam. 1 Eye Damage Category 1

Eye Irr. 2 Eye Irritation Category 2

Oxid. Sol. 1 Oxidizing Solid Category 1

Repr. 1A Reproductive Toxicity Category 1A

Repr. 1B Reproductive Toxicity Category 1B

Skin Corr. 1B Skin Corrosion Category 1B

STOT RE 1 Specific Target Organ Toxicity Repeated Exposure Category 1

STOT SE 3 Specific Target Organ Toxicity Single Exposure Category 3

H300 Fatal if swallowed

H301 Toxic if swallowed.

H310 Fatal in contact with skin.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H318 Causes serious eye damage.

H319 Causes serious eye irritation

H330 Fatal if inhaled.

H335 May cause respiratory irritation

H350 Fatal if inhaled.

H351 Suspected of causing cancer.

H360 May damage fertility or the unborn child.

H271 May cause damage to organs.

H372 Causes damage to organs through prolonged or repeated exposure.

H373 May cause damage to organs through prolonged or repeated exposure.

Supersedes: 24 February 2017

Date updated: 28 December 2017

Revision Summary: Corrected part numbers in Section 1.1.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, ECHA REACH Registration Website, Country websites for occupational exposure limits.