

SAFETY DATA SHEETS

This SDS packet was issued with item:

074383113

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

075982103 075982152

DENTSPLY International

Prosthetics

Safety Data Sheet

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

Date Issued: 13 October 1997
Document Number: 135
Date Revised: 7 February 2019
Revision Number: 7

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

1.1 Product Identifier:

Trade Name (as labeled): Orthostone Dental Stone
Part/Item Number: 99206, 99207

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

Recommended Use: For Investing and Fabrication of Dental Casts
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

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
Carcinogen Category 2 (H351)	Not Hazardous	Not Hazardous

2.2 Label Elements:



Signal Word: Warning

Contains: Titanium dioxide

Hazard Phrases	Precautionary Phrases
H351 Suspected of causing cancer by inhalation.	P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P280 Wear protective gloves, protective clothing, eye protection and face protection. P308 + P313 If exposed or concerned: Get medical advice or attention. P405 Store locked up. P501 Dispose of contents and container in accordance with local and national regulations.

2.3 Other Hazards: None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixture

Hazardous Components	C.A.S. #	EINECS # / REACH Registration #	Classification	WT %
Calcium Sulfate Hemihydrate	26499-65-0	231-900-3 /	Not applicable	97-99
Titanium dioxide	13463-67-7	236-675-5	Carc. 2 (H351)	1-3

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

4. FIRST AID MEASURES

4.1 Description of First Aid Measures:

Eye	Flush eyes with water, while holding the eyelids apart. Get medical attention if irritation occurs or persists.
Skin	No first aid is generally required. Wash skin with soap and water after use.
Inhalation	Remove victim to fresh air. If irritation or other symptoms persist, get medical attention.
Ingestion	If swallowed, get immediate medical attention. Product hardens in contact with water and will cause intestinal obstruction.

4.2 Most Important Symptoms and Effects, Both Acute and Delayed:

May cause eye and skin irritation. Inhalation of dust may cause mucous membrane and respiratory irritation. May cause gastrointestinal discomfort and intestinal blockage. When mixed with water, this material hardens and becomes very hot – may cause burns. Contains an ingredient that may cause cancer by inhalation.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:

Immediate medical attention may be required if large amounts are ingested.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media: Use media that is suitable for the surrounding fire.

5.2 Special Hazards Arising from the Substance or Mixture:

When mixed with water, this material hardens and becomes very hot – may cause burns. Thermal decomposition (above 1450°C) may generate calcium oxide and sulfur dioxide.

5.3 Advice for Fire-Fighters:

Fire Fighting Procedures/Precautions for Fire Fighters:

Use water to cool fire exposed containers. Firefighters should wear full emergency equipment and approved positive pressure self-containing breathing apparatus

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Avoid contact with eyes and skin. Do not breathe dust. Wear appropriate protective clothing as described in Section 8. For dusty conditions wear suitable respiratory equipment.

6.2 Environmental Precautions:

Avoid releases to the environment. Report releases as required by local and national authorities.

6.3 Methods and Material for Containment and Cleaning up:

Sweep or vacuum up, taking care not to generate airborne dust and place in appropriate container for use. Do not use compressed air.

6.4 Reference to Other Sections:

Refer to Section 8 for Personal Protective Equipment and Section 13 for Disposal information.

7. HANDLING AND STORAGE

7.1 Precautions for Safe Handling:

Avoid contact with the eyes and skin. Do not breathe dust. Wear protective clothing and equipment as described in Section 8. Use with adequate ventilation and proper dust collection methods to keep exposure level below occupational exposure limits. Wash thoroughly with soap and water after handling. Keep containers closed when not in use.

7.2 Conditions for Safe Storage, Including Any Incompatibilities:

Store in a cool, dry, well-ventilated area away from incompatible materials. Protect from physical damage. Keep containers closed when not in use.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

Occupational Exposure Limits:

Calcium Sulfate Hemihydrate	5 mg/m ³ (respirable), 15 mg/m ³ (total dust) TWA OSHA PEL 10 mg/m ³ (inhalable) TWA ACGIH TLV (as Calcium sulfate)
	1.5 mg/m ³ (respirable fraction), 4 mg/m ³ (inhalable fraction) TWA DFG MAK (as Calcium sulfate)
	10 mg/m ³ (Inhalable aerosol), 4 mg/m ³ (Respirable aerosol) TWA UK WEL
	Belgium: 10 mg/m ³ TWA (as Calcium sulfate)
Titanium dioxide	15 mg/m ³ TWA OSHA PEL (Total dust) 10 mg/m ³ TWA ACGIH TLV
	4 mg/m ³ TWA WEL (respirable dust) 10 mg/m ³ TWA WEL (inhalable dust)
	Belgium: 10 mg/m ³ TWA

Biological Exposure Limits: None Established

8.2 Exposure Controls:

Appropriate Engineering Controls: Use adequate general or local exhaust ventilation to maintain exposures below the occupational exposure limits.

Individual Protection Measures (PPE):

Specific Eye/face Protection: Safety glasses or goggles if needed to avoid eye contact.

Specific Skin Protection: Wear rubber or other impervious gloves to avoid prolonged or repeated contact.

Specific Respiratory Protection: If the exposure limits are exceeded an approved particulate respirator appropriate for the form and concentration of the contaminants should be used. Selection and use of respiratory equipment must be in accordance with all applicable regulations and good industrial hygiene practice.

Specific Thermal Hazards: None required.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	White powder	Explosive limits:	LEL: Not determined UEL: Not determined
Odor:	No odor	Vapor pressure (mmHg):	Not applicable
Odor threshold:	None	Vapor density: (Air = 1)	Not applicable
pH:	Not applicable	Relative density:	2.6-3.2

Melting/freezing point:	Decomposes	Solubility(ies):	In water: Nil
Initial boiling point and boiling range:	Not applicable	Partition coefficient: n-octanol/water:	Not applicable
Flash point:	Not applicable	Auto-ignition temperature:	Not applicable
Evaporation rate: (n-BuAc = 1)	Not applicable	Decomposition temperature:	Not determined
Flammability (solid, gas):	Not flammable	Viscosity:	Not applicable
Explosive Properties:	Non-explosive	Oxidizing Properties:	None

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: None known.

10.2 Chemical Stability: Hygroscopic – absorbs water or moisture from the air.

10.3 Possibility of Hazardous Reactions: Contact with water causes product to harden and become hot.

10.4 Conditions to Avoid: Avoid exposure to water or moisture from air.

10.5 Incompatible materials: Aluminum (+ heat), diazomethane, and acids.

10.6 Hazardous Decomposition Products: Thermal decomposition will generate calcium oxide and toxic sulfur dioxide.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: Contact with dust may cause mechanical irritation and possible injury.

Skin: May cause mechanical irritation. When this product is mixed with water, the material hardens and becomes hot – may cause skin burns.

Ingestion: No adverse effects expected for normal, incidental ingestion. Large amounts may cause gastrointestinal irritation, gastrointestinal discomfort and blockage.

Inhalation: Inhalation of dust may cause irritation to the nose, throat and upper respiratory tract with coughing and shortness of breath.

Chronic Health Effects: Prolonged or repeated skin contact may cause dermatitis.

Irritation: No data available for Calcium Sulfate Hemihydrate. Calcium sulfate: Not irritating to rabbit skin and to rabbit eyes.

Corrosivity: This product is not classified as corrosive. When mixed with water, this material hardens and becomes very hot – may cause burns.

Sensitization: No data available for Calcium Sulfate Hemihydrate. Calcium sulfate: Was negative in a Buehler test with guinea pigs.

Carcinogenicity: This product contains a Titanium dioxide that is listed by IARC as a Category 2B Carcinogen (Possibly carcinogenic to humans.) 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 for Calcium Sulfate Hemihydrate. Calcium sulfate: Was negative in the AMES test and an in vitro mammalian cell gene mutation assay.

Aspiration Hazard: Not an aspiration hazard.

Acute Toxicity Data:

Calcium Sulfate Hemihydrate: Oral rat LD50 -> 2000 mg/kg; Inhalation rat LC50- > 3.26 mg/L/4 hr.

Reproductive Toxicity Data: In a 7 day reproductive screening test, rats were administered orally up to 1000 mg/kg. No adverse reproductive or developmental effects were seen. NOEL 790 mg/kg.

Specific Target Organ Toxicity Single Exposure (STOT-SE):

No data is currently available.

Specific Target Organ Toxicity Repeated Exposure (STOT-RE):

No data is currently available.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

No data available. This material is not expected to be toxic to plants or aquatic organisms.

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

12.3 Bio-accumulative Potential: The potential for bioaccumulation is expected to be low.

12.4 Mobility in Soil: No data is 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 national and local regulations.

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
DOT	None	Not Regulated	None	None	Not applicable
ADR/RID	None	Not Regulated	None	None	Not applicable
IMDG	None	Not Regulated	None	None	Not applicable
IATA/ICAO	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 is not subject to CERCLA reporting requirements. 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 (CAS number 7778-18-9).

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

Clean Air Act (CAA): This material is not 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: WARNING. Cancer – www.P65Warnings.ca.gov

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.

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

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

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

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

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:

Carc. 2 Carcinogen Category 2

H351 May cause cancer by inhalation.

Supersedes: 2 November 2018

Date Updated: 7 February 2019

Revision Summary: Changes to Section 2, 3, 8, 11.

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