SAFETY DATA SHEETS

This SDS packet was issued with item:

070640037

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

070639971 070701516 070744672 070747212 070747220 070828657 070828665 072759009 273002309 273045759 273045760

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

070702803 070889626 072742286 072759017 273002310

DENTSPLY International
DENTSPLY PROSTHETICS

Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010)

Date Issued: 5 January 2004
Document Number: 179
Date Revised: 30 September 2011
Revision Number: 3

1. PRODUCT IDENTIFICATION

Trade Name (as labeled):	**Lucitone® Clear Dental Resin Powder**
Product Identifier (Part/Item Number):	**688542, 688506, 688502**
U.N. Number:	**None**
U.N. Dangerous Goods Classification:	**None**
Recommended Use:	**Resin used in removable dental appliances.**
Restrictions on Use:	**For Professional Use Only**
Manufacturer/Supplier Name:	**Dentsply Prosthetics**
Manufacturer/Supplier Address:	**570 West College Ave.**
	York, PA 17405-0872
Manufacturer/Supplier Telephone Number:	**717-845-7511 (Product Information)**
Emergency Contact Telephone Number:	**800-424-9300 Chemtrec**
Email address:	**Prosthetics_MSDS@Dentsply.com**

2. HAZARD(s) IDENTIFICATION

EU Classification (1999/45/EC): Not Classified as Hazardous

Labeling in accordance with 1999/45/EC: None required

US Hazard Classification: Not Hazardous

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Components	C.A.S. #	EINECS #	Substance Classification	WT %
Polymethylmethacrylate	Proprietary	Proprietary	Not applicable	90 - 100

4. FIRST-AID MEASURES

Routes of Exposure	First Aid Instructions
Eye	Immediately flush victim's eyes with large quantities of water, holding the eyelids apart. Get medical attention if irritation persists.
Skin	Remove contaminated clothing. Wash skin thoroughly with soap and water. Get medical attention if irritation develops. Launder clothing before re-use.
Inhalation	Remove victim to fresh air. If breathing is difficult have qualified personnel administer oxygen. Get medical attention if symptoms persist.
Ingestion	If conscious, wash mouth out with water. Do not induce vomiting. Never give anything by mouth to an unconscious or convulsing person. Get medical attention.
Most important symptoms of exposure	Dust may cause mild eye and respiratory irritation.
Note to Physicians (Treatment, Testing, and Monitoring): Treat symptomatically.	

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media:	Water fog, carbon dioxide dry chemical. Do not use a water stream. Water stream can disperse dust in air producing a fire hazard and possible explosion hazard if exposed to ignition source.
Fire Fighting Procedures:	Cool exposed intact containers with water spray.
Specific Hazards Arising from the Chemical:	High concentrations of dust in air may be explosive.
Precautions for Fire Fighters:	Firefighters should wear full emergency equipment and approved positive pressure self-containing breathing apparatus.

Recommended Protective Equipment for Fire Fighters:

EYES/FACE	HANDS	RESPIRATORY	THERMAL
			

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, PPE and Emergency Procedures: Wear appropriate protective clothing as described in Section 8. Remove all sources of ignition. Caution: Spilled powder can be a slip hazard. Avoid contact with skin, eyes or clothing.
Environmental Precautions: Do not allow spills to enter sewers or waterways. Report releases as required by local, state, and national authorities.
Methods and Materials for Containment and Clean-up: Carefully collect and place into a container for disposal. Do not generate airborne dust.

Recommended Personal Protective Equipment for Containment and Clean-up:			
EYES/FACE	**HANDS**	**RESPIRATORY**	**THERMAL**
			

7. HANDLING AND STORAGE

Precautions for Safe Handing: Avoid contact with eyes and skin. Do not breathe dust. Wash thoroughly after handling. Wear protective clothing and equipment as described in Section 8. Use with adequate ventilation. Use good housekeeping to minimize accumulation of dust on equipment and surfaces. Keep away from sources of heat or ignition sources.

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

Conditions for Safe Storage: Store in a cool, dry, well ventilated area. Keep container tightly closed when not in use. Store away from oxidizers.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits:		
Polymethylmethacrylate	United States	15 mg/m3 TWA OSHA PEL (Total Dust) 5 mg/m3 TWA OSHA PEL (Respirable)
	Germany	4 mg/m3 TWA MAK (Inhalable), 1.5 mg/m3 TWA MAK (Respirable)
	United Kingdom	10 mg/m3 TWA UK OEL (Inhalable), 4 mg/m3 TWA UK OEL (Respirable)
	European Union	None Established

Biological Exposure Limits: None established.

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

Individual Protection Measures (PPE)

Specific Eye/face Protection: Safety glasses goggles.

Specific Skin Protection: Wear impervious gloves such as rubber if needed to avoid prolonged skin contact. Recommended glove: rubber. Consult glove supplier for thickness and breakthrough times.

Specific Respiratory Protection: None needed for normal use. 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

Recommended Personal Protective Equipment			
EYES/FACE	**HANDS**	**RESPIRATORY**	**THERMAL**
			
Environmental Exposure Controls: None required for normal use.			
General Hygiene Considerations and Work Practices: Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling.			
Protective Measures During Repair and Maintenance of Contaminated Equipment: Wear appropriate protective clothing and equipment.			

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	**White free-flowing powder.**	**Explosive limits:**	**LEL: 20 g/m^3** **UEL: Not applicable**
Odor:	**Not available.**	**Vapor pressure:**	**Not applicable**
Odor threshold:	**Not determined**	**Vapor density:**	**Not applicable**
pH:	**Not applicable**	**Relative density:**	**Not available**
Melting/freezing point:	**Not applicable**	**Solubility:**	**Insoluble**
Initial boiling point and range:	**Not applicable**	**Partition coefficient: n-octanol/water:**	**Not applicable**
Flash point:	**>392°F (>200°C)**	**Auto-ignition temperature:**	**>392°F (>200°C)**
Evaporation rate:	**Not applicable**	**Decomposition temperature:**	**>392°F (>200°C)**
Flammability:	**Non flammable**	**Viscosity:**	**Not applicable**
Explosive Properties:	**High concentrations of dust in air may be explosive.**	**Oxidizing Properties:**	**None**

10. STABILITY AND REACTIVITY

Reactivity: None known

Chemical Stability: Stable.
Possibility of Hazardous Reactions: None known
Conditions to Avoid: Excessive heat (temperatures greater than 392°F (300°C). Keep away heat, sparks or ignition sources.
Incompatible materials: Avoid oxidizing agents.
Hazardous Decomposition Products: Thermal decomposition may release carbon oxides and methyl methacrylate.

11. TOXICOLOGICAL INFORMATION

Potential Health Effects: Eyes: Dust may cause irritation with abrasive injury. Skin: No adverse effects are normally expected. Ingestion: Small amounts are not expected to cause adverse effects. Inhalation: Inhalation of dust may cause irritation of the nose, throat and upper respiratory tract.
Chronic Health Effects: None currently known.
Carcinogenicity: None of the components of this product are listed as carcinogens by OSHA, IARC or NTP or the EU Substances Directive.
Mutagenicity: No data available. This product is not expected to cause mutagenic activity.
Medical Conditions Aggravated by Exposure: Individuals with pre-existing skin and respiratory disorders may be at increased risk from exposure.
Acute Toxicity Data: Polymethylmethacrylate: Oral rat LD50 >5000 mg/kg
Reproductive Toxicity Data: No data available. This product is not expected to cause adverse reproductive effects.
Specific Target Organ Toxicity (STOT): Single Exposure: Polymethylmethacrylate is non-irritating to eye and skin. Repeated Exposure: No data available

12. ECOLOGICAL INFORMATION

Toxicity: No data available
Persistence and Degradability: No data available
Bio-accumulative Potential: No data available
Mobility in Soil: No data available
Other Adverse Effects: No data available

Results of PBT/vPvB Assessment: No data available

13. DISPOSAL CONSIDERATIONS

Regulations: Dispose in accordance with all national and local regulations.
Properties (Physical/Chemical) Affecting Disposal: None currently known.
Waste Treatment Recommendations: None known.

14. TRANSPORT INFORMATION

UN Number:	ADR/RID: None	IMDG: None	IATA: None	DOT: None
UN proper shipping name:	ADR/RID: Not Regulated IMDG: Not Regulated IATA: Not Regulated DOT: Not Regulated			
Transport hazard class(es):	ADR/RID: None	IMDG: None	IATA: None	DOT: None
Packaging group:	ADR/RID: None	IMDG: None	IATA: None	DOT: None
Environmental hazards:	ADR/RID: No	IMDG Marine pollutant: No	IATA: No	DOT: No
Special precautions for user: Not applicable				

15. REGULATORY INFORMATION

U.S. Federal Regulations

US OSHA Hazard Classification: Non-hazardous.

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): This product is a medical device and not subject to chemical notification requirements.

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:

Immediate Hazard:	**No**	**Pressure Hazard:**	**No**
Delayed Hazard:	**No**	**Reactivity Hazard:**	**No**
Fire Hazard:	**No**		

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

Components	C.A.S. #	WT %
None		

State Regulations

California: This product contains the following substances known to the state of California to cause cancer and/or reproductive toxicity: None.

Components	C.A.S. #	WT %
None		

International Regulations

Canadian Environmental Protection Act: All of the components in this product are listed on the Domestic Substances List (DSL).

Canadian Workplace Hazardous Materials Information System (WHMIS): Not a controlled product.

European Inventory of Existing Chemicals (EINECS): This product is a medical device and not subject to chemical notification requirements.

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

Australian Inventory of Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

China Inventory of Existing Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Japanese Existing and New Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Korean Existing Chemicals List: This product is a medical device and not subject to chemical notification requirements.

Philippine Inventory of Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

16. OTHER INFORMATION

HMIS Hazard Rating:
Health –0 Flammability – 1 Reactivity – 0

Full text of Classification abbreviations used in Section 2 and 3: None.

Supersedes: 29 May 2008

Revision Summary: Change in format. Comprehensive review. Changes to all sections.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau, ESIS, Country websites for occupational exposure limits.

DENTSPLY International
DENTSPLY PROSTHETICS

Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010)

Date Issued: 5 January 2004
Document Number: 179
Date Revised: 26 June 2015
Revision Number: 6

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

1.1 Product Identifier:

Trade Name (as labeled): **Lucitone® Clear Dental Resin Powder**

Part/Item Number: **688542, 688506, 688502**

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

Recommended Use: **Resin used in removable dental appliances.**

Restrictions on Use: **For Professional Use Only**

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name: **DENTSPLY Prosthetics**

Manufacturer/Supplier Address: **570 West College Ave.**
York, PA 17401

Manufacturer/Supplier Telephone Number: **717-845-7511 (Product Information)**

Email address: **Prosthetics_MSDS@Dentsply.com**

1.4 Emergency Telephone Number:

Emergency Contact Telephone Number: **800-424-9300 Chemtrec**

2. HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS Classification:

Health	Environmental	Physical
Not Hazardous	Not Hazardous	Not Hazardous

EU Classification: Not classified as dangerous

OSHA Specific Hazards: Combustible Dust

2.2 Label Elements:

Signal Word: Warning

Hazard Phrases	Precautionary Phrases
May form combustible dust concentrations in air.	P210 Keep away from heat, sparks, open flames, and hot surfaces.-No smoking.

2.3 Other Hazards: None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixture:

Hazardous Components	C.A.S. #	EINECS #	Classification	WT %
Polymethylmethacrylate	Proprietary	Proprietary	Not applicable	90-100

The exact concentration is being withheld as a trade secret.

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

4. FIRST AID MEASURES

4.1 Description of First Aid Measures:	
Eye	Immediately flush victim's eyes with large quantities of water, holding the eyelids apart. Get medical attention if irritation persists.
Skin	Wash skin with soap and water. Remove contaminated clothing and shoes. Get medical attention if irritation or symptoms of exposure occurs. Launder clothing before re-use.
Inhalation	Remove victim to fresh air. If breathing is difficult have qualified personnel administer oxygen. Get medical attention if symptoms persist.
Ingestion	If conscious, wash mouth out with water. Do not induce vomiting. Never give anything by mouth to an unconscious or convulsing person. Get medical attention.
4.2 Most Important Symptoms and Effects, Both Acute and Delayed:	
Dust may cause mild eye and respiratory irritation. Individuals with sensitivity to methacrylates may develop an allergic reaction when exposed to this product for prolonged periods.	
4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:	
Immediate medical attention should not be required.	
Note to Physicians (Treatment, Testing, and Monitoring): Treat symptomatically.	

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media:	Water fog, carbon dioxide dry chemical. Do not use a water stream. Water stream can disperse dust in air producing a fire hazard and possible explosion hazard if exposed to ignition source.
5.2 Special Hazards Arising from the Substance or Mixture:	
Dust generated in processing of this material may present a potential fire and explosion hazard if suspended in air at high concentrations. Settled dust presents a fire hazard. Re-suspension of the dust into the air by vibration, traffic, material handling, etc. in high concentrations in the presence of an ignition source could result in a dust explosion. Minimize the generation and accumulation of dust. Thermal decomposition may release carbon oxides and methyl methacrylate.	
5.3 Advice for Fire-Fighters:	
Fire Fighting Procedures:	Cool fire exposed containers and structures with water. Do not use solid water jet as that may create a dust cloud that can present an explosion hazard.

Precautions for Fire Fighters:	Firefighters should wear full emergency equipment and approved positive pressure self-contained breathing apparatus. Do not enter fire area without proper protection.

Recommended Protective Equipment for Fire Fighters:			
EYES/FACE	**HANDS**	**RESPIRATORY**	**THERMAL**
			

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Evacuate spill area and keep unprotected personnel away. Eliminate all sources of ignition. Avoid contact with skin, eyes or clothing. Avoid breathing dust. Wear appropriate protective clothing as described in Section 8. Powders that become wet may cause surfaces to be extremely slippery and present a slip hazard.

Recommended Personal Protective Equipment for Containment and Clean-up:			
EYES/FACE	**HANDS**	**RESPIRATORY**	**SKIN**
			

6.2 Environmental Precautions:

Do not allow water to enter lakes, streams, ponds, groundwater or soil. Report releases as required by local and national authorities.

6.3 Methods and Material for Containment and Cleaning up:

Scoop or shovel up using methods that minimize the generation of airborne dust. Non-sparking tools should be used. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentrations. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Place dry material into an appropriate container for disposal. Flush spill area with water to remove residue.

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 Handing:

Avoid contact with the eyes, skin and clothing. Avoid breathing dust. Wear protective clothing and equipment as described in Section 8. Use with adequate ventilation. Wash thoroughly with soap and water after handling. Minimize the generation and accumulation of dust. Keep dust away from open flames, hot surfaces and sources of ignition. Follow good housekeeping practices to keep surfaces, including areas overhead such as piping, drop ceilings, ductwork, etc. free from settled dust. Dry powders can build static electricity charges when subjected to friction of transfer and in mixing operations.

Provide adequate precautions, such as electrical grounding and bonding.

Do not reuse containers. 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 cool, dry, well-ventilated area away from heat and sources of ignition. Keep container tightly closed when not in use. Keep away from oxidizing agents and other incompatible materials.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

Occupational Exposure Limits:

Polymethylmethacrylate	United States	15 mg/m^3 TWA, 5 mg/m^3 (respirable fraction) OSHA PEL (total dust) (As PNOC)
	Germany	4 mg/m^3 TWA DFG (inhalable fraction) (as Dust, inhalable)
	United Kingdom	None Established
	European Union	Belgium: 10 mg/m^3 TWA (as Dust, inhalable)

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. Provide local exhaust ventilation where product is processed in a manner that generates dust. It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling this product contain explosion relief vents or an explosion suppression system or an oxygen deficient environment. Ensure that dust handling systems (such as exhaust ducts, dust collectors, vessels and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e. there is no leakage from the equipment). Use only appropriately classified electrical equipment.

Individual Protection Measures (PPE):

Specific Eye/face Protection: Wear chemical safety glasses or tight fitted goggles if needed to avoid eye contact.
Specific Skin Protection: For prolonged use or in dusty conditions, wear rubber gloves.
Specific Respiratory Protection: None should be needed for normal use. If the exposure limits are exceeded, an approved respirator with dust/mist cartridges or supplied air respirator appropriate for the form and concentration of the contaminants should be used. Selection and use of respiratory equipment must be in accordance with applicable regulations and good industrial hygiene practice.
Specific Thermal Hazards: None required

Recommended Personal Protective Equipment

EYES/FACE	HANDS	RESPIRATORY	SKIN
			

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	White powder.	**Explosive limits:**	**LEL:** 20 g/m^3 **UEL:** Not applicable
Odor:	Not available.	**Vapor pressure (mmHg):**	Not applicable
Odor threshold:	Not determined	**Vapor density:**	Not applicable
pH:	Not applicable	**Relative density:**	Not available
Melting/freezing point:	Not applicable	**Solubility(ies):**	Insoluble
Initial boiling point and boiling range:	Not applicable	**Partition coefficient: n-octanol/water:**	Not applicable
Flash point:	>392°F (>200°C)	**Auto-ignition temperature:**	>392°F (>200°C)
Evaporation rate:	Not applicable	**Decomposition temperature:**	>392°F (>200°C)
Flammability (solid, gas):	Polymer dust is combustible	**Viscosity:**	Not applicable
Explosive Properties:	High concentrations of dust in the presence of an ignition source could result in a dust explosion.	**Oxidizing Properties:**	None

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: None known.

10.2 Chemical Stability: Stable.

10.3 Possibility of Hazardous Reactions: None known.

10.4 Conditions to Avoid: Avoid heat, sparks, flames and all other sources of ignition. Avoid hygroscopic conditions and dust formation. Avoid excessive temperatures greater than 392°F (200°C).

10.5 Incompatible materials: Avoid oxidizing agents.

10.6 Hazardous Decomposition Products: Thermal decomposition may release carbon oxides and methyl methacrylate.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:
Eyes: Dust may cause irritation with redness and tearing.
Skin: Dust may cause mechanical irritation. Individuals with sensitivity to methacrylates may develop an allergic reaction.
Ingestion: Swallowing large amounts may cause nausea, vomiting and diarrhea.
Inhalation: Inhalation of dust may cause irritation of the nose, throat and upper respiratory tract.

Chronic Health Effects: None currently known.

Irritation: No data available. This product may cause mechanical irritation.

Corrosivity: This product is not classified as corrosive.

Sensitisation: Individuals with sensitivity to methacrylates may develop an allergic reaction.

Carcinogenicity: None of the components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU Directive.

Mutagenicity: No data available.

Medical Conditions Aggravated by Exposure:
Individuals with pre-existing skin and respiratory disorders may be at increased risk from exposure.

Acute Toxicity Data:
Polymethylmethacrylate: Oral rat LD50 >5000 mg/kg

Reproductive Toxicity Data: No data available

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

Repeated Exposure: No data available.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:
No ecotoxicity data available.

12.2 Persistence and Degradability: No data is currently available

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:

Regulations: Dispose in accordance with all national and local regulations.
Properties (Physical/Chemical) Affecting Disposal: Follow all SDS precautions when handling empty containers.
Waste Treatment Recommendations: Treat 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	None
ADR/RID	None	Not Regulated	None	None	None
IMDG	None	Not Regulated	None	None	None
IATA/ICAO	None	Not Regulated	None	None	None

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): This product is a medical device and not subject to chemical notification requirements.

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:

Immediate Hazard:	No	**Pressure Hazard:**	No
Delayed Hazard:	No	**Reactivity Hazard:**	No
Fire Hazard:	Yes		

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):

Components	C.A.S. #	WT %
None		

State Regulations

California: This product contains the following substances known to the state of California to cause cancer and/or reproductive toxicity:

Components	C.A.S. #	WT %
None		

International Regulations

Canadian Workplace Hazardous Materials Information System (WHMIS): Medical devices are not subject to WHMIS.

Canadian Environmental Protection Act: This product is a medical device and not subject to chemical notification requirements.

This SDS has been prepared according to the criteria of the Controlled Products Regulation (CPR) and the SDS contains all of the information required by the CPR.

European Inventory of Existing Chemicals (EINECS): This product is a medical device and not subject to chemical notification requirements.

EU REACH: This product is a medical device and not subject to chemical notification requirements.

Australian Inventory of Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

China Inventory of Existing Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Philippine Inventory of Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Korean Existing Chemicals List: This product is a medical device and not subject to chemical notification requirements.

15.2 Chemical Safety Assessment: None required.

16. OTHER INFORMATION

HMIS Hazard Rating:
Health – 0 Flammability – 2 Physical Hazard– 0

Full text of Classification abbreviations used in Section 2 and 3:
None

Supersedes: 26 February 2015
Date Revised: 26 June 2015
Revision Summary: Removed errant phrase.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau, ESIS, Country websites for occupational exposure limits.

Dentsply Sirona
Prosthetics

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: 8 August 2016
Document Number: 600
Date Revised: N/A
Revision Number: New

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

1.1 Product Identifier:

Trade Name (as labeled):	**Lucitone® HIPA Denture Base Powder**
Part/Item Number:	**905922-905929, 905932-905939, 905942-905949, 905952, 905954, 905956, 906018-906022**

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

Recommended Use:	**Denture base material**
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:	**800-424-9300 Chemtrec**

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
May form combustible dust concentrations in air. 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. P308+P313 IF exposed or concerned: Get medical 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 %
Non-hazardous ingredients	Proprietary	Proprietary	Not applicable	Balance
Dibenzoyl peroxide*	94-36-0	202-327-6 /	Skin Sens. 1, H317 Org. Perox. B, H241 Eye Irrit. 2, H319 Aquatic Acute 1, H400 (M-Factor Acute: 10) Aquatic Chronic 1, H410 (M-Factor Chronic: 10)	<1
Titanium Dioxide	13463-67-7	236-675-5	Carc. 2, H351	<1

*The Dibenzoyl peroxide is inextricable bound in the product matrix; hence, no exposure to dibenzoyl peroxide can occur.

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

4.1 Description of First Aid Measures:	
Eye	Rinse thoroughly with water, while holding the eye lids open to be sure the material is washed out. Get medical attention if irritation occurs and persists.
Skin	Remove clothing. Wash skin thoroughly with soap and water. Get medical attention if irritation develops. Launder contaminated clothing before re-use.

Inhalation	If irritation develops, remove to fresh air. Get medical attention if symptoms persist.
Ingestion	Do not induce vomiting unless directed to do so by a medical professional. If conscious, wash mouth out with water. Never give anything by mouth to an unconscious or convulsing person. Get medical attention if symptoms develop.

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

May cause eye and skin irritation. This product contains titanium dioxide which is suspected of causing cancer. Risk of cancer depends on level and duration of exposure.

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

Immediate medical attention should not be required.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media:	On large fires, use dry chemical, foam, or water spray. For small fires, use carbon dioxide, dry chemical, or water spray. Do not use solid water jet as that may create a dust cloud that can present an explosion hazard.

5.2 Special Hazards Arising from the Substance or Mixture:

Avoid generating dust. Concentrated dust/air combinations may produce explosive conditions. As with all organic dusts, fine particles suspended in air in critical proportions and in the presence of an ignition source may ignite and/or explode. Dust may be sensitive to ignition by electrostatic discharge, electrical arcs, sparks, welding torches, cigarettes, open flame, or other significant heat sources. As a precaution, implement standard safety measures for handling finely divided organic powders. Decomposition may release oxides of carbon and methyl methacrylate.

5.3 Advice for Fire-Fighters:

Fire Fighting Procedures/Precautions for Fire Fighters:	Cool fire exposed containers and structures with water. Firefighters should wear full emergency equipment and approved positive pressure self-contained breathing apparatus. Do not enter fire area without proper protection. Contain water used in firefighting from entering sewers or natural waterways.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Avoid contact with skin, eyes or clothing. Avoid breathing dust or fumes. Wear appropriate protective clothing as described in Section 8. Avoid creating and breathing dust. Eliminate ignition sources.

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:

Wet down and collect in a manner to minimize the generation of airborne dusts or vacuum with a high efficiency vacuum cleaner. If a vacuum is used, explosion proof equipment is required. Non-sparking tools should be used. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentrations. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air.) Non-sparking tools should be used.

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 Handing:

Avoid contact with the eyes, skin and clothing. Avoid breathing dust. Wear protective clothing and equipment as described in Section 8. Avoid creating and breathing dusts. Use only with adequate ventilation. Wash thoroughly with soap and water after handling. Minimize the generation and accumulation of dust. Keep dust away from open flames, hot surfaces and sources of ignition. Follow good housekeeping practices to keep surfaces, including areas overhead such as piping, drop ceilings, ductwork, etc. free from settled dust. Dry powders can build static electricity charges when subjected to friction of transfer and in mixing operations. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

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 cool, dry, well-ventilated area. Store away from incompatible materials and protect from physical damage.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

Occupational Exposure Limits:

Non Hazardous ingredients	None Established
Dibenzoyl peroxide	5 mg/m^3 TWA ACGIH TLV 5 mg/m^3 TWA OSHA PEL 5 mg/m^3 TWA DFG MAK (inhalable), 5 mg/m^3 STEL (inhalable) 5 mg/m^3 TWA UK WEL
Titanium Dioxide	10 mg/m^3 TWA ACGIH TLV 15 mg/m^3 TWA OSHA PEL (total dust) 10 mg/m^3 (Inhalable), 4 mg/m^3 (respirable) TWA UK WEL 10 mg/m^3 TWA Belgium OEL

Biological Exposure Limits: None Established

8.2 Exposure Controls:

Appropriate Engineering Controls: Use with adequate general or local exhaust ventilation to maintain exposures below occupational exposure limits. It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen deficient environment. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). Use only appropriately classified electrical equipment and powered industrial trucks.

Individual Protection Measures (PPE):

Specific Eye/face Protection: Chemical safety glasses or goggles recommended.

Specific Skin Protection: Wear impervious gloves to prevent skin contact. Consult glove supplier for thickness

and breakthrough times.
Specific Respiratory Protection: None should be needed for normal use. If exposure limits are exceeded, an approved respirator with dust/mist cartridges or supplied air respirator appropriate for the form and concentration of the contaminants should be used. Selection and use of respiratory equipment must be in accordance with 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:	Colored free flowing powder	**Explosive limits:**	**LEL:** Not applicable **UEL:** Not applicable
Odor:	Faint methacrylate odor.	**Vapor pressure (mmHg):**	Not applicable
Odor threshold:	Not determined	**Vapor density:**	Not applicable
pH:	Not applicable	**Relative density:**	Not available
Melting/freezing point:	Not applicable	**Solubility:**	Insoluble
Initial boiling point and range:	Not applicable	**Partition coefficient: n-octanol/water:**	Not applicable
Flash point:	>392°F (>200°C)	**Auto-ignition temperature:**	>932°F (>500°C)
Evaporation rate:	Not applicable	**Decomposition temperature:**	>392°F (>200°C)
Flammability:	Non flammable	**Viscosity:**	Not applicable
Explosive Properties:	May shatter glass containers due to pressure build up.	**Oxidizing Properties:**	Not oxidizing

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: Polymerization will not occur.
10.2 Chemical Stability: Stable under normal condition.
10.3 Possibility of Hazardous Reactions: None known.
10.4 Conditions to Avoid: Avoid excessive heat, flames, ignition sources and direct sunlight.
10.5 Incompatible materials: Oxidizing agents.
10.6 Hazardous Decomposition Products: Decomposition may release oxides of carbon and methyl methacrylate.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:
Eyes: Dust may cause irritation with redness and tearing.
Skin: May cause irritation.
Ingestion: Swallowing large amounts may cause nausea, vomiting and diarrhea.
Inhalation: Inhalation of dust may cause irritation of the nose, throat and upper respiratory tract.

Chronic Health Effects: None expected under normal use.

Irritation: None expected under normal use.

Corrosivity: This product is not classified as corrosive.

Sensitization: Dibenzoyl Peroxide: Dibenzoyl peroxide is a skin sensitizer; however, it is inextricably bound in the product and no exposure will occur.

Carcinogenicity: Titanium dioxide: Titanium dioxide is listed by IARC as a Group 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. This product is not expected to cause mutagenic activity.

Acute Toxicity Data:
Non Hazardous ingredients : Not acutely toxic
Dibenzoyl Peroxide: Oral rat LD50 > 5000 mg/kg, inhalation rat LC0: 24.3 mg/L

Reproductive Toxicity Data: No data available. This product is not expected to cause adverse reproductive effects.

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:
Dibenzoyl Peroxide: Oncorhynchus mykiss LC50: 0.0602 mg/L/96hr

This product is not expected to cause harm to the environment.

12.2 Persistence and Degradability: Dibenzoyl peroxide 68% in 28 days.

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: Treat 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	None
ADR/RID	None	Not Regulated	None	None	None
IMDG	None	Not Regulated	None	None	None
IATA/ICAO	None	Not Regulated	None	None	None

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): Releases above the RQ of 500,000 lbs (based on the RQ for Benzoic Acid of 5,000 lbs present at <1%) 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.

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: Chronic Health, Fire Hazard

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):

Components	C.A.S. #	WT %
Dibenzoyl peroxide	94-36-0	<1%

State Regulations

California: This product contains substances known to the state of California to cause cancer and/or reproductive toxicity.

15.2 Chemical Safety Assessment: None required.

16. OTHER INFORMATION

HMIS Hazard Rating:
Health – 1* Flammability – 2 Physical Hazard– 0

Full text of Classification abbreviations used in Section 2 and 3:
Aquatic Acute 1 Aquatic Acute Toxicity Category 1
Aquatic Chronic 1 Aquatic Chronic Toxicity Category 1
Carc. 2 Carcinogen Category 2
Eye Irrit. 2 Eye Irritant Category 2
Org. Perox. B Organic Peroxide Type B
Skin Sens. 1 Skin Sensitizer Category 1
H241 Heating may cause a fire or explosion.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H351 Suspected of causing cancer.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

Supersedes: None
Date Updated: 8 August 2016
Revision Summary: New SDS

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

Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing and Handling of Combustible Particulate Solids, for safe handling.