

SAFETY DATA SHEETS

This SDS packet was issued with item:

072742286

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

072759009

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).

070640037 072759017

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 Handling: 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/m ³ TWA OSHA PEL (Total Dust) 5 mg/m ³ TWA OSHA PEL (Respirable)
	Germany	4 mg/m ³ TWA MAK (Inhalable), 1.5 mg/m ³ TWA MAK (Respirable)
	United Kingdom	10 mg/m ³ TWA UK OEL (Inhalable), 4 mg/m ³ 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: <u>Eyes:</u> Dust may cause irritation with abrasive injury. <u>Skin:</u> No adverse effects are normally expected. <u>Ingestion:</u> Small amounts are not expected to cause adverse effects. <u>Inhalation:</u> 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): <u>Single Exposure:</u> Polymethylmethacrylate is non-irritating to eye and skin. <u>Repeated Exposure:</u> 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

Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010), US 29CFR1910.1200, Canada Hazardous Products Regulation

Date Issued: 13 September 2006

Document Number: 200

Date Revised: 3 August 2017

Revision Number: 6

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

1.1 Product Identifier:

Trade Name (as labeled): Eclipse® Gel

Part/Item Number: 905049

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

Recommended Use: Processing Aid for Fabricating Eclipse Dentures

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
Eye Irritant Category 2 (H319) Skin Irritant Category 2 (H315) Skin Sensitization Category 1 (H317)	Not Hazardous	Not Hazardous

2.2 Label Elements:



Signal Word: Warning

Contains: Aliphatic Urethane Methacrylate

Hazard Phrases	Precautionary Phrases
H315 Causes skin irritation. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation.	P261 Avoid breathing mist or vapor. P264 Wash thoroughly after handling. P272 Contaminated work clothing should not be allowed out of the workplace. P280 Wear protective gloves, protective clothing, eye protection and face protection. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 If eye irritation persists: Get medical attention. P302+P352 IF ON SKIN: Wash with plenty of soap and water. P333+P313 If skin irritation or rash occurs: Get medical attention. P362 Take off contaminated clothing and wash before reuse. 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 %
Aliphatic Urethane Methacrylate	Proprietary	Proprietary	Eye Irrit. 2A, H319 Skin Irrit. 2, H315 Skin Sens. 1, H317	80-100%
Amorphous Precipitated Silica	112945-52-5	231-545-4 /	Not Applicable	1-10%

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	Immediately flush eyes with large quantities of water for at least 15 minutes, while holding the eyelids apart. Get medical attention if irritation persists.
Skin	Remove contaminated clothing. Wash skin thoroughly with soap and water. If rash, irritation or symptoms develop, get medical attention. Launder clothing before re-use. (Discard contaminated shoes).
Inhalation	If irritation develops, remove to fresh air. Get medical attention if symptoms persist.

Ingestion	If small quantities are swallowed, wash mouth with water. Do not induce vomiting. Never give anything by mouth to an unconscious or drowsy person. Get medical attention if symptoms develop or if you feel unwell.
4.2 Most Important Symptoms and Effects, Both Acute and Delayed:	
May cause moderate eye and skin irritation. May cause skin sensitization.	
4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:	
Immediate medical attention is not required.	

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media:	Use water fog, foam, carbon dioxide, water spray or dry chemical.
5.2 Special Hazards Arising from the Substance or Mixture:	
High temperatures may cause a polymerizing reaction to occur. Closed containers may rupture or explode during runaway polymerization. Decomposition may release acrid smoke or fumes, carbon and nitrogen oxides.	
5.3 Advice for Fire-Fighters:	
Fire Fighting Procedures/Precautions for Fire Fighters:	Cool exposed intact containers with water spray. Firefighters should wear full emergency equipment and an approved positive pressure self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:	
Evacuate spill area and keep unprotected personnel away. Avoid contact with skin, eyes or clothing. Avoid breathing vapors or mists. Ventilate area. Wear appropriate protective clothing as described in Section 8.	
6.2 Environmental Precautions:	
Prevent entry into sewers and waterways. Report releases as required by local, state and federal authorities.	
6.3 Methods and Material for Containment and Cleaning up:	
Exposure to sunlight or artificial light will cause the gel to polymerize into hard plastic. Spread the gel to maximize the surface area. Once the material is hard, pick up and place into a container for disposal.	
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, skin and clothing. Wear protective clothing and equipment as described in Section 8. Avoid breathing vapors or mists. Use with adequate ventilation. Wash thoroughly with soap and water after handling. Keep containers closed when not in use. Keep out of the reach of children.	

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. Material is light sensitive, do not store in direct sunlight. Do not store near high temperatures or ignition sources. Prevent contact with moisture. Refrigeration prolongs shelf life. 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:

Aliphatic Urethane Methacrylate	None Established
Amorphous Precipitated Silica	20 mppcf TWA OSHA PEL
	4 mg/m ³ TWA DFG MAK (Inhalable)
	6 mg/m ³ (Inhalable), 2.4 mg/m ³ (respirable) TWA UK WEL

Biological Exposure Limits: None Established

8.2 Exposure Controls:

Appropriate Engineering Controls: Use with adequate local exhaust ventilation to maintain exposures below the occupational exposure limits and when grinding polymerized (cured) material.

Individual Protection Measures (PPE):

Specific Eye/face Protection: Chemical safety goggles recommended.

Specific Skin Protection: Impervious gloves such as rubber recommended.

Specific Respiratory Protection: None should be needed for normal use. If the exposure limits are exceeded, or ventilation is inadequate, 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:	Clear, colorless viscous gel	Explosive limits:	LEL: Not applicable UEL: Not applicable
Odor:	Slight ester odor.	Vapor pressure (mmHg):	<1 mmHg
Odor threshold:	Not available	Vapor density:	>1
pH:	Not applicable	Relative density:	1.2

Melting/freezing point:	<-40°C (<-40°F)	Solubility(ies):	Negligible in water
Initial boiling point and boiling range:	Not available	Partition coefficient: n-octanol/water:	Not available
Flash point:	Not flammable	Auto-ignition temperature:	Not available
Evaporation rate:	Not available	Decomposition temperature:	Not available
Flammability (solid, gas):	Not applicable	Viscosity:	90,000 cps @ 40°C (104°F)
Explosive Properties:	Closed containers may explode due to runaway polymerization.	Oxidizing Properties:	None

9.2 Other Information: None available.

10. STABILITY AND REACTIVITY

10.1 Reactivity: Will react when exposed to heat or light.
10.2 Chemical Stability: Stable under normal conditions.
10.3 Possibility of Hazardous Reactions: Hazardous polymerization will occur when exposed to high temperatures, sunlight, or artificial light.
10.4 Conditions to Avoid: Avoid excessive heat, flames, ignition sources and direct sunlight.
10.5 Incompatible materials: Oxidizing agents, reducing agents, free radical imitators, inert gases and oxygen scavengers. Avoid excessive heat, flames, ignition sources and direct sunlight.
10.6 Hazardous Decomposition Products: Decomposition may release acrid smoke or fumes, carbon and nitrogen oxides.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

<p><u>Potential Health Effects:</u></p> <p><u>Eyes:</u> Contact may cause irritation with redness, tearing and stinging. Repeated contact may cause moderate irritation.</p> <p><u>Skin:</u> May cause irritation with redness and rash. Repeated contact may cause moderate irritation with redness and swelling. May cause an allergic skin reaction or sensitization.</p> <p><u>Ingestion:</u> None expected under normal conditions of use.</p> <p><u>Inhalation:</u> None expected under normal conditions of use.</p> <p><u>Chronic Health Effects:</u> None known.</p> <p><u>Irritation:</u> No data available. This product is expected to cause eye and skin irritation.</p> <p><u>Corrosivity:</u> No data available. This product is not expected to be corrosive.</p> <p><u>Sensitization:</u> No data available. This product is expected to cause sensitization.</p> <p><u>Carcinogenicity:</u> None of the components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the</p>

EU CLP.
Mutagenicity: No data available. This product is not expected to cause mutagenic activity.
Acute Toxicity Data: Aliphatic Urethane Methacrylate: No toxicity data available. Amorphous Precipitated Silica: Oral rat LD50- >10,000 mg/kg; Inhalation rat LC50- >0.139 mg/l/4h (highest concentration – no deaths); Skin rabbit LD50- >5000 mg/kg
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.
Aspiration Hazard: Not an aspiration hazard

12. ECOLOGICAL INFORMATION

12.1 Toxicity: Amorphous Precipitated Silica: 24h EC50 Daphnia Magna: >10,000 mg/l; 96h LC50 Zebra Fish: >10,000 mg/l This product is not expected to cause environmental toxicity.
12.2 Persistence and Degradability: No data available.
12.3 Bio-accumulative Potential: No data available.
12.4 Mobility in Soil: No data 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	No
ADR/RID	None	Not Regulated	None	None	No

IMDG	None	Not Regulated	None	None	No
IATA/ICAO	None	Not Regulated	None	None	No

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 – product is transported only in packaged form.

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.

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: Refer to Section 2 for OSHA Hazard Classification.

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: None known.

International Regulations

Canadian Environmental Protection Act: This product contains components that are not 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: One or more of the components in this product are not listed on the AICS for Australia.

China Inventory of Existing Chemicals and Chemical Substances: One or more of the components in this product are not listed on the IECSC for China.

Japanese Existing and New Chemical Substances: One or more of the components in this product are not listed on Japanese ENCS lists.

Korean Existing Chemicals List: One or more of the components in this product are not listed on the KECL for Korea.

Philippine Inventory of Chemicals and Chemical Substances: One or more of the components in this product are not listed on the PICCS.

15.2 Chemical Safety Assessment: None required.

16. OTHER INFORMATION

HMIS Hazard Rating:

Health – 2 Flammability – 0 Physical Hazard– 1

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

Eye Irrit. 2A Eye Irritant Category 2A

Skin Irrit. 2 Skin Irritant Category 2

Skin Sens. 1 Skin Sensitization 1

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

Supersedes: 7 May 2014

Date Updated: 3 August 2017

Revision Summary: 3 Year Update. Section 1, Manufacturer Name, Section 16 SARA 311/312

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

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: 5 January 2004
Document Number: 179
Date Revised: 7 August 2018
Revision Number: 7

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 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
Not Hazardous	Not Hazardous	Not Hazardous

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 # / REACH Registration #	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 Classifications.

4. FIRST AID MEASURES

4.1 Description of First Aid Measures:

Eye	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.

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/Precautions
for Fire Fighters:**

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

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.

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 Handling:

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.

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	15 mg/m ³ TWA, 5 mg/m ³ (respirable fraction) OSHA PEL (total dust) (As PNOC)
	4 mg/m ³ TWA DFG (inhalable fraction) (as Dust, inhalable)
	Belgium: 10 mg/m ³ TWA (as Dust, inhalable)
Biological Exposure Limits: None Established	
8.2 Exposure Controls:	
<p>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.</p>	
<p>Individual Protection Measures (PPE):</p> <p>Specific Eye/face Protection: Wear chemical safety glasses or tight fitted goggles if needed to avoid eye contact.</p> <p>Specific Skin Protection: For prolonged use or in dusty conditions, wear rubber gloves.</p> <p>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.</p> <p>Specific Thermal Hazards: None required</p>	

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: (Air = 1)	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: (n-BuAc = 1)	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 CLP.

Mutagenicity: No data available.

Aspiration Hazard: Not an aspiration hazard

Acute Toxicity Data:

Polymethylmethacrylate: Oral rat LD50 >5000 mg/kg

Reproductive Toxicity Data: No data available

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:

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:

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: See OSHA Hazard Classification in Section 2.

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: None known

International Regulations

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

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 June 2015

Date Revised: 7 August 2018

Revision Summary: Updated Section 1, 11, and 15.

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