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: 20 November 1985
Document Number: 150
Date Revised: 25 November 2019
Revision Number: 5

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

1.1 Product Identifier:

Trade Name (as labeled): **Lucitone 199® Denture Base Powder**

Part/Item Number: **688103, 688203, 688303, 688403, 688105, 688205, 688305, 688405, 688106, 688206, 688306, 688406, 688111, 688211, 688311, 688411, 688102, 688107, 688120, 688220, 688320, 688420**

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 Classification: Combustible Dust

2.2 Label Elements:

Signal Word: Warning.

May form combustible dust concentrations in air.

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, while holding the eyelids apart. Get medical attention if irritation persists.
Skin	Wash skin thoroughly with soap and water. Get medical attention if irritation occurs.
Inhalation	Remove victim to fresh air. If breathing is difficult have qualified personnel administer oxygen. Get medical attention if symptoms persist.
Ingestion	Rinse mouth out with water. Seek medical attention if large amounts are swallowed.

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.

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, carbon dioxide, or dry chemical.

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-containing 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. Do not breathe 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 spills to enter sewers or waterways. 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. Do not breathe 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.

Empty containers retain product residues. 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, sources of ignition and incompatible materials. Keep container tightly closed when not in use. Keep away from oxidizing agents.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:	
Occupational Exposure Limits:	
Polymethylmethacrylate	5 mg/m^3 (respirable), 15 mg/m^3 (total dust) TWA OSHA PEL (As PNOC)
	4 mg/m^3 TWA DFG MAK (Inhalable) (As Dust, general threshold limit value)
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 safety glasses or goggles where eye contact is possible.

Specific Skin Protection: Wear impervious gloves such as rubber to avoid skin contact.

Specific Respiratory Protection: 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	Pink free flowing powder	**Explosive limits:**	**LEL:** 20 g/m³ **UEL:** Not determined
Odor:	Faint methacrylate odor	**Vapor pressure (mmHg):**	Not applicable
Odor threshold:	Not determined	**Vapor density:** (Air = 1)	Not applicable
pH:	Not applicable	**Relative density:**	Not determined
Melting/freezing point:	Not applicable	**Solubility(ies):**	Not soluble
Initial boiling point and boiling range:	Not applicable	**Partition coefficient: n-octanol/water:**	Not applicable
Flash point:	572°F (300°C)	**Auto-ignition temperature:**	>570°F (>299°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 heat (temperatures greater than 392°F (200°C).

10.5 Incompatible materials: 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 mechanical irritation with redness and tearing.
Skin: Dust may cause mild irritation.
Ingestion: May cause gastrointestinal irritation with nausea, vomiting and diarrhea.
Inhalation: Inhalation of dust may cause irritation of the nose, throat and upper respiratory tract.

Chronic Health Effects: Prolonged or repeated overexposure may cause mild skin irritation.

Irritation: This product is not expected to cause eye or skin irritation.

Corrosivity: No data available. This product is not expected to be corrosive.

Sensitization: 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 CLP.

Mutagenicity: No data available.

Aspiration Hazard: Not an aspiration hazard.

Acute Toxicity Data:
Polymethylmethacrylate: Not acutely toxic.

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:
Benzoyl Peroxide: 96 hr LC50 Rainbow Trout – 0.0602 mg/L; 48 hr EC50 Daphnia magna- 0.0602 mg/L

12.2 Persistence and Degradability: This product is expected to not be biodegradable.

12.3 Bio-accumulative Potential: No data available

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): 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 titanium dioxide which is known to the state of California to cause cancer. However, the titanium dioxide is inextricably bound within the chemical matrix of the product and no exposure can occur.

International Regulations

Canadian Environmental Protection Act: 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.

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.

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:
None.

Supersedes: 10 November 2016
Date Updated: 25 November 2019
Revision Summary: 3 year update: Removal of BPO. Changes to All Sections.

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.