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: 20 November 1985
Document Number: 150
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Revision Number: 4

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: **800-424-9300 Chemtrec**

2. HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS Classification:

Health	Environmental	Physical
Skin Sensitizer Category 1 (H317)	Not Hazardous	Not Hazardous

OSHA Specific Classification: Combustible Dust

2.2 Label Elements:

Signal Word: Warning

Contains: Benzoyl Peroxide

Hazard Phrases	Precautionary Phrases
May form combustible dust concentrations in air. H317 May cause an allergic skin reaction.	P210 Keep away from heat, sparks, and open flames. No smoking. P261 Avoid breathing dust. P272 Contaminated work clothing must not be allowed out of the workplace. P280 Wear protective gloves, protective clothing, eye protection or face protection. P302+P352 IF ON SKIN: Wash with plenty of soap and water. P333+P313 If skin irritation or rash occurs: Get medical attention. P363 Wash contaminated clothing 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 %
Polymethylmethacrylate	Proprietary	Proprietary	Not applicable	90-100
Benzoyl Peroxide	94-36-0	202-327-6 /	Org. Perox. Type B, H241 Eye Irrit. 2A, H319 Skin Sens. 1, H317 Aqua Acute 1, H400 Aqua Chronic 1, H410	<0.5

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	Remove contaminated clothing. Wash skin thoroughly with soap and water. Get medical attention if irritation or rash 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. May cause skin sensitization. Individuals with sensitivity to methacrylates may also 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. 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, 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)
Benzoyl Peroxide	5 mg/m^3 TWA ACGIH TLV 5 mg/m^3 TWA OSHA PEL
	5 mg/m^3 TWA (Inhalable), 5 mg/m^3 STEL (Inhalable) DFG MAK
	5 mg/m^3 TWA UK WEL
	Belgium: 5 mg/m^3 TWA
Biological Exposure Limits: None Established	

8.2 Exposure Controls:
Appropriate Engineering Controls: Use adequate general or local exhaust ventilation to maintain exposures below the occupational exposure limits. 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:**	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:	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 irritation, redness, rash and swelling. May cause skin sensitization in sensitive individuals.
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 skin irritation or sensitization in some individuals.

Irritation: Benzoyl Peroxide: Not irritating to rabbit skin and was moderately irritating to rabbit eyes after 24 hours. This product is not expected to cause eye or skin irritation.

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

Sensitization: Benzoyl Peroxide: Benzoyl peroxide was found to be sensitizing in a mouse local lymphnode assay (LLNA). 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: No toxicity data available.

Benzoyl Peroxide: Oral rat LD50 –>5,000 mg/kg; Inhalation rat LD50 ->24.3 mg/L/4hr

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: Benzoyl Peroxide: Readily biodegradable in screening tests – 68% in 28 days. 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: Acute Health**.**

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: Titanium Dioxide (<0.1 %.)

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.

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 – 2 Flammability – 2 Physical Hazard– 0

Full text of Classification abbreviations used in Section 2 and 3:
Aqua Acute 1 Aquatic Acute Toxicity Category 1
Aqua Chronic 1 Aquatic Chronic Toxicity Category 1
Eye Irrit. 2A Eye Irritant Category 2A
Org. Perox. Type B Organic Peroxide Category 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.
H400 Very toxic to aquatic life
H410 Very toxic to aquatic life with long lasting effects

Supersedes: 14 January 2014
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Revision Summary: 3 year update: Changes to Sections 1, 3, 11, & 16

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