# **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:

<b>GHS Classification:</b>		
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.	P201 Obtain special instructions before use.
H351 Suspected of causing cancer by inhalation.	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 # /	Classification	WT %
		REACH		
		Registration #		
Non-hazardous ingredients	Proprietary	Proprietary	Not applicable	Balance
Dibenzoyl peroxide*	94-36-0	202-327-6 /	Skin Sens. 1, H317	<1
			Org. Perox. B, H241	
			Eye Irrit. 2, H319	
			Aquatic Acute 1, H400	
			(M-Factor Acute: 10)	
			Aquatic Chronic 1, H410	
			(M-Factor Chronic: 10)	
Titanium Dioxide	13463-67-7	236-675-5	Carc. 2, H351	<1

<sup>\*</sup>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/m³ TWA ACGIH TLV 5 mg/m³ TWA OSHA PEL 5 mg/m³ TWA DFG MAK (inhalable), 5 mg/m³ STEL (inhalable) 5 mg/m³ TWA UK WEL			
Titanium Dioxide	10 mg/m³ TWA ACGIH TLV 15 mg/m³ TWA OSHA PEL (total dust) 10 mg/m³ (Inhalable), 4 mg/m³ (respirable) TWA UK WEL 10 mg/m³ 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
рН:	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.

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

<u>Carcinogenicity:</u> 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	14.2 UN Proper Shipping	14.3	14.4 Packing	14.5 Environmental
	Number	Name	Hazard	Group	Hazards
			Class(s)	_	
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.