SAFETY DATA SHEETS

This SDS packet was issued with item:

072760064

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

072760007 072760015 072760023 072760031 072760049 072760056 072760072 072760080 072760098 072760114 072760122 072760130 072760148 072760262 072760270 072760288 072760296 072760304 072760312 072760320 072760338

DENTSPLY International

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: 16 February 1996
Document Number: 169
Date Revised: 2 August 2017
Revision Number: 6

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

1.1 Product Identifier:

Trade Name (as labeled):	**Lucitone® Characterized Denture Base Resin**
Part/Item Number:	**686004, 686031, 686042-043, 686045-046, 686056, 686120, 686123-124, 686130, 686133-134, 686140, 686144, 686143, 686371, 686373, 686376**

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
Eye Irritant Category 2 (H319) Reproductive Toxicity Category 1B (H360Df) Skin Irritant Category 2 (H315) Specific Target Organ Toxicity – Single Exposure Category 3 (H335)	Aquatic Chronic Toxicity Category 3 (H412)	Not Hazardous

OSHA Specific Classification: Combustible Dust

2.2 Label Elements:

Signal Word: Danger

Contains: Dibutyl Phthalate

Hazard Phrases	Precautionary Phrases
May form combustible dust concentrations in air. H315 Causes skin irritation. H319 Causes serious eye irritation. H335 may cause respiratory irritation. H360Df May damage the unborn child. Suspected of damaging fertility. H412 Harmful to aquatic life with long lasting effects**.**	P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P210 Keep away from heat, sparks, and open flames. No smoking. P261 Avoid breathing dust. P264 Wash thoroughly after handling. P271 Use only outdoors or in a well-ventilated area. P273 Avoid release to the environment. P280 Wear protective gloves, 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. P332+P313 If skin irritation occurs: Get medical attention. P362 Take off contaminated clothing and wash before reuse. P304+P340 IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. P312 Call a POISON CENTER or doctor if you feel unwell. P308 + P313 IF exposed or concerned: Get medical attention. P403 + P233 Store in a well-ventilated place. Keep container tightly closed. 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 %
Polymethyl Methacrylate and Acrylic Copolymers	Mixture	Mixture	Eye Irrit. 2A, H319 Skin Irrit. 2, H315 STOT SE 3, H335	85-100

Dibutyl Phthalate	84-74-2	201-557-4 /	Repr. 1B, H360Df Aq. Acute 1, H400 Aq. Chronic 2, H411	0-15

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 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 irritation or symptoms develop, get medical attention. 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	Do not induce vomiting unless directed to do so by medical personnel. If conscious, give 8 ounces of water to dilute. 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:	
Causes eye, skin and respiratory irritation. This product contains Dibutyl Phthalate, which may cause adverse reproductive effects based on studies with laboratory animals. 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 should not be required.	

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media:	Use water fog, carbon dioxide, 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 methacrylate monomers.	
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 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. 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 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. 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:	
Polymethyl Methacrylate and Acrylic Copolymers	5 mg/m^3 (respirable), 15 mg/m^3 (total dust) TWA OSHA PEL (As PNOC)
	10 mg/m^3 TWA (as Dust, inhalable) Belgium
	4 mg/m3 TWA DFG MAK (Inhalable) (As Dust, general threshold limit value)
Dibutyl Phthalate	5 mg/m^3 TWA ACGIH TLV 5 mg/m^3 TWA OSHA PEL
	0.58 mg/m^3 TWA (Inhalable fraction and vapor), 1.16 mg/m^3 STEL (15 minute reference period) DFG MAK
	5 mg/m^3 TWA UK OEL 10 mg/m^3 STEL UK OEL
	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: Chemical safety glasses with side shields or chemical goggles recommended.

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

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

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	Pink free flowing powder	**Explosive limits:**	**LEL:** 20 m/m³ **UEL:** Not applicable
Odor:	Faint methacrylate odor	**Vapor pressure (mmHg):**	Not applicable
Odor threshold:	Not available	**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 available
Flash point:	572°F (300°C) TCC	**Auto-ignition temperature:**	Not available
Evaporation rate:	Not applicable	**Decomposition temperature:**	392°F (200°C)
Flammability (solid, gas):	Polymer dust is combustible	**Viscosity:**	Not available
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: Non-reactive under normal conditions.

10.2 Chemical Stability: Stable under normal conditions.

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 572°F (300°C)).

10.5 Incompatible materials: Avoid oxidizing agents.

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

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 irritation, redness, rash and swelling. May cause skin sensitization in sensitive individuals.
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: Repeated skin contact may cause dermatitis.

Irritation: Dibutyl Phthalate: Not irritating to rabbit skins and eyes.

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

Sensitization: Individuals with sensitivity to methacrylates may develop an allergic reaction. Dibutyl Phthalate was not sensitizing in a guinea pig maximization test.
Carcinogenicity: None of the components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU CLP.
Mutagenicity: Dibutyl Phthalate: Negative in an in vitro bacterial gene mutation assay.
Aspiration Hazard: Not an aspiration hazard
Acute Toxicity Data: Polymethyl Methacrylate and Acrylic Copolymers: No data available Dibutyl Phthalate: Oral rat LD50- 6279 mg/kg; Skin rabbit LD50- 4200 mg/kg; Inhalation rat LC50- > 15.68 mg/L/4 hr
Reproductive Toxicity Data: Dibutyl phthalate: Has been shown to cause adverse reproductive effects and birth defects in a two generation study with rats. The effects on the second generation were greater than on the first generation. The lowest dose-level in this study, 0.1% in the diet (52 mg/kg by weight for males; 80 mg/kg by weight for females) is a LOAEL for embryotoxicity. The NOAEL for maternal toxicity is 0.5% in the diet (385 mg/kg by weight).
Specific Target Organ Toxicity Single Exposure (STOT-SE): No data currently available.
Specific Target Organ Toxicity Repeated Exposure (STOT-RE): Dibutyl phthalate: In animal studies, dibutyl phthalate has been shown to cause kidney and liver damage, fetotoxicity, teratogenicity, and testicular damage.

12. ECOLOGICAL INFORMATION

12.1 Toxicity: Dibutyl Phthalate: 96 hr LC50 Fathead minnow-0.92 mg/L; 48 hr EC50 Daphnia magna- 4.8 mg/L; 96 hr EC50 Pseudokirchnerella subcapitata- 0.75 mg/L
12.2 Persistence and Degradability: Dibutyl phthalate: Had an average aerobic and anaerobic biodegradation half-life of 2.9 and 14.4 days, respectively.
12.3 Bio-accumulative Potential: No data available.
12.4 Mobility in Soil: Dibutyl phthalate is expected to have a low mobility in soil.
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	14.4 Packing Group	14.5 Environmental 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): This product has a Reportable Quantity (RQ) of 66 lbs. (based on the RQ for Dibutyl Phthalate of 10 lbs present at 0-15%). Releases above the RQ 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.

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): Dibutyl Phthalate is regulated under the Clean Air Act

Superfund Amendments and Reauthorization Act (SARA) Title III Information:

SARA Section 311/312 (40 CFR 370) Hazard Categories: Classified under OSHA Hazcom 2012 GHS as per Section 2 of this SDS.

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

Components	C.A.S. #	WT %
Dibutyl Phthalate	84-74-2	0-15%

State Regulations

California: WARNING: WARNING: This product can expose you to chemicals including Titanium dioxide, which is known to the state of California to cause cancer, and Di-n-butyl phthalate, which is known to the State of California to cause birth defects and other reproductive harm. For more information go to www.P65Warnings.ca.gov.

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 – 2* Flammability – 2 Physical Hazard– 0

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
STOT SE 3 Specific Target Organ Toxicity Single Exposure Category 3
Repro 1B Toxic to Reproduction Category 1B
Aq. Acute 1 Aquatic Acute Toxicity Category 1
Aq. Chronic 2 Aquatic Chronic Toxicity Category 2
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 may cause respiratory irritation.
H360Df May damage the unborn child. Suspected of damaging fertility.
H400 Very toxic to aquatic life.
H411 Toxic to aquatic life with long lasting effects**.**

Supersedes: 18 March 2014

Date Updated: 2 August 2017

Revision Summary: 3 Year update. 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.