SAFETY DATA SHEETS

This SDS packet was issued with item:

070876391

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

070876409 070876417 070876425 070876516

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).

070889626 273002310

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: 31 August 2016 Document Number: 604 Date Revised: None Revision Number: New SDS

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

1.1 Product Identifier:

Trade Name (as labeled): Lucitone® Intensive Colors
Part/Item Number: 905990, 905992 - 905996

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

Recommended Use: Used to modify the shade of 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 | |
| Carcinogen Category 2 (H351) | Not Hazardous | Not Hazardous | |
| (White Shade Only) | | | |

OSHA Specific Classification: Combustible Dust

2.2 Label Elements:

| The label elements below are for the White Shade Only: | The label elements below are for the Red, Yellow, Brown, and Blue Shades: |
|---|---|
| | |
| Signal Word: Warning | |
| Contains: Titanium dioxide | Signal Word: Warning |
| Hazard Phrases | Hazard Phrases |
| May form combustible dust concentrations in air. | May form combustible dust concentrations in air. |
| H351 Suspected of causing cancer by inhalation. | |
| Precautionary Phrases | Precautionary Phrases |
| P201 Obtain special instructions before use. | None Required |
| 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 | 90-<100 |
| Titanium Dioxide (in White Shade Only) | 13463-67-7 | 236-675-5 | Carc. 2, H351 | <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 | 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. Wash mouth out with water. Get medical attention if symptoms develop. |

4.2 Most Important Symptoms and Effects, Both Acute and Delayed:

Dust may cause mechanical eye and respiratory irritation. The white shade 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: Use water fog, carbon dioxide or dry chemical. Do not use a water stream.

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. 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. 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:

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.

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: | | |
| Non Hazardous ingredients | None Established | |
| 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: No | ne 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 if needed to avoid eye contact.

Specific Skin Protection: For prolonged use or in dusty conditions, wear rubber gloves.

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: | Negligible in water | |
| Initial boiling point and range: | Not applicable | Partition coefficient: n-octanol/water: | Not applicable | |
| Flash point: | Not applicable | Auto-ignition temperature: | >869°F (>465°C) | |
| Evaporation rate: | Not applicable | Decomposition temperature: | Not available | |
| Flammability: | Combustible dust | Viscosity: | Not applicable | |
| Explosive Properties: | High concentrations of dust in the presence of an ignition source could result in a dust explosion. | 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 heat, sparks, flames and all other sources of ignition. Avoid hygroscopic conditions and dust formation.

10.5 Incompatible materials: Oxidizing agents, reducing agents, acids, bases and amines.

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: May cause irritation with redness and tearing.

Skin: May cause irritation.

<u>Ingestion:</u> Swallowing large amounts may cause nausea, vomiting and diarrhea.

Inhalation: Inhalation may cause irritation of the nose, throat and upper respiratory tract.

Chronic Health Effects: None expected under normal use.

<u>Irritation:</u> This product is not classified as an irritant. This product may cause mechanical eye and respiratory tract irritation.

Corrosivity: This product is not classified as corrosive.

Sensitization: This product contains residual Benzoyl peroxide which is a skin sensitizer. However, it is inextricably bound in the product and under normal handling will not constitute a hazard. If the product is dissolved in organic solvent, chemical residues may be released.

<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

Titanium Dioxide: Oral rat LD50 ->5000 mg/kg, Inhalation rat LC50->6.82 mg/L/4 hr

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:

This product is not expected to cause harm to the environment.

- 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.

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): None

State Regulations

California: This product contains the following chemicals that are known to the State of California to cause cancer, birth defects or other reproductive harm: Titanium Dioxide <5%

15.2 Chemical Safety Assessment: None required.

16. OTHER INFORMATION

HMIS Hazard Rating:

Health -1* Flammability -2 Physical Hazard -0

*Chronic Health Hazard

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

Carc. 2 Carcinogen Category 2 H351 Suspected of causing cancer.

Supersedes: None

Date Updated: 31 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.