# SAFETY DATA SHEETS

## This SDS packet was issued with item:

071253236

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

071253202

# 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: 21 June 2019
Document Number: 672
Date Revised: N/A
Revision Number: New

## 1. DENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

**1.1 Product Identifier:**

**Trade Name (as labeled):** **Lucitone Digital Fuse™ Step 2 - 3D Denture Bonding Agent**

**Part/Item Number:** **906186 - 906192**

**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:** **800-243-1942**

## 2. HAZARDS IDENTIFICATION

**2.1 Classification of the Substance or Mixture:**

**GHS Classification:**

| Health | Environmental | Physical |
|---|---|---|
| Eye Damage Category 1 (H318)<br>Reproductive Toxicity Category 2 (H361df)<br>Skin Sensitization Category 1B (H317) | Aquatic Chronic Toxicity Category 2 (H411) | Not Hazardous |

**2.2 Label Elements:**

**Signal Word:** Warning

Contains: Urethane Methacrylate, Organic methacrylate and acrylate monomers, photoinitiator, Methacrylic Acid

| Hazard Phrases | Precautionary Phrases |
|---|---|
| H317 May cause an allergic skin reaction.<br>H318 Causes serious eye damage.<br>H361 Suspected of damaging fertility or the unborn child.<br>H411 Toxic to aquatic life with long lasting effects. | P201 Obtain special instructions before use.<br>P202 Do not handle until all safety precautions have been read and understood.<br>P261 Avoid breathing mists, vapors, or spray.<br>P272 Contaminated work clothing must not be allowed out of the workplace.<br>P273 Avoid release to the environment.<br>P280 Wear protective gloves, protective clothing, and eye protection.<br>P308 + P313 IF exposed or concerned: Get medical advice or attention.<br>P302 + P352 IF ON SKIN: Wash with plenty of soap and water.<br>P333+P313 If skin irritation or rash occurs: Get medical attention<br>P362 + P364 Take off contaminated clothing and wash it before reuse.<br>P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.<br>P310 Immediately call a POISON CENTER or doctor.<br>P391 Collect spillage.<br>P405 Store locked up.<br>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 % |
|---|---|---|---|---|
| Urethane Methacrylate | Proprietary | Proprietary | Not Hazardous | 40-50 |
| Organic Methacrylate Monomer | Proprietary | Proprietary | Skin Sens. 1B, H317<br>Aq. Chronic 2, H411 | 40-50 |
| Organic Acrylate Monomer | Proprietary | Proprietary | Eye Dam. 1, H318<br>Skin Sens. 1B, H317<br>Aq. Chronic 2, H411 | 1-5 |
| Photoinitiator | Proprietary | Proprietary | Skin Sens. 1B, H317<br>Repr. 2, H361df<br>Aq. Chronic 2, H411 | <1.5 |

| | | | | |
|---|---|---|---|---|
| Methacrylic Acid | Proprietary | Proprietary | Acute Tox. 4 ,H302<br>Acute Tox. 3, H311<br>Skin Corr. 1A, H314<br>Eye Dam 1, H318<br>Acute Tox. 4, H332<br>STOT SE 3, H335 | <1 |

**Refer to Section 16 for the full text of the GHS Classifications.**

## 4. FIRST AID MEASURES

| **4.1 Description of First Aid Measures:** | |
|---|---|
| **Eye** | Immediately flush eyes with large quantities of water for at least 15 minutes, while holding the eyelids apart. Get immediate medical attention. |
| **Skin** | Remove clothing. Wash skin thoroughly with soap and water. Get medical attention if irritation or rash 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. If conscious, wash mouth out with water. Never give anything by mouth to an unconscious or convulsing person. Get medical attention if you feel unwell. |

| **4.2 Most Important Symptoms and Effects, Both Acute and Delayed:** |
|---|
| Causes serious eye irritation with possible damage. May cause skin irritation. Prolonged or repeated contact may cause allergic skin reaction. Individuals with sensitivity to methacrylates may develop an allergic reaction when exposed to this product. This product contains a component that is suspected of damaging fertility or the unborn child based on animal studies. |

| **4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:** |
|---|
| Immediate medical attention is required for eye contact. |
| **Note to Physicians (Treatment, Testing, and Monitoring):** Treat symptomatically. |

## 5. FIRE-FIGHTING MEASURES

| | |
|---|---|
| **5.1 Extinguishing Media:** | Use water fog, foam, carbon dioxide, water spray or dry chemical. |

| **5.2 Special Hazards Arising from the Substance or Mixture:** |
|---|
| High temperatures and sunlight may cause a polymerizing reaction to occur. Decomposition may release acrid smoke or fumes, carbon and nitrogen oxides. |

| **5.3 Advice for Fire-Fighters:** | |
|---|---|
| **Fire Fighting Procedures:** | Cool fire exposed containers and structures with water. |
| **Precautions for Fire Fighters** | 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:**

Prevent further leakage or spillage if you can do so without risk. Avoid breathing vapors or mists. Avoid contact with skin, eyes or clothing. Wear appropriate protective clothing.

**6.2 Environmental Precautions:**

Report spills and releases as required to appropriate authorities.

**6.3 Methods and Material for Containment and Cleaning up:**

Exposure to sunlight or artificial light will cause the resin to polymerize. Spread the paste to maximize the surface area. Once the material is hard, pick up and place into a container for disposal. Wash spill area thoroughly.

**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 Handling:**

Avoid contact with skin, eyes or clothing. Wear protective clothing and equipment. Avoid breathing mists or vapors. Use with adequate ventilation. Wash thoroughly with soap and water after handling. Do not expose to direct sunlight. Keep containers closed when not in use.

Do not reuse containers. Empty containers retain product residues and contaminants that 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 location away from incompatible materials, such as strong oxidizing agents, strong reducing agents, inert gas, oxygen scavengers, and peroxides. Do not store in direct sunlight. Protect from physical damage. Keep container tightly closed when not in use.

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

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**8.1 Control Parameters:**

**Occupational Exposure Limits:**

| | |
|---|---|
| Urethane Methacrylate | None Established |
| Organic methacrylate monomer | None Established |
| Photoiniator | None Established |
| Organic acrylate monomer | None Established |
| Methacrylic Acid | 20 ppm TWA ACGIH TLV<br>50 ppm TWA 100 ppm STEL DFG MAK<br>20 ppm TWA 40 ppm STEL UK WEL |
| Refer to local regulations for exposure limits not listed above.<br><br>**Biological Exposure Limits:** None Established | |

**8.2 Exposure Controls:**

**Appropriate Engineering Controls:** Use with adequate general or local exhaust ventilation to maintain exposure levels below the occupational exposure limits or when grinding polymerized (cured) materials.

**Individual Protection Measures (PPE):**

**Specific Eye/face Protection:** Chemical safety goggles recommended. In the EU refer to EN 166.

**Specific Skin Protection:** Wear impervious gloves to prevent skin contact. In the EU refer to EN 374.

**Specific Respiratory Protection:** None should be needed for normal use. When grinding, polishing or where exposure levels are excessive, 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 viscous liquid | **Explosive limits:** | **LEL:** No data available<br>**UEL:** No data available |
| **Odor:** | Characteristic ester-like odor | **Vapor pressure (mmHg):** | No data available |
| **Odor threshold:** | Not available | **Vapor density: (Air=1)** | No data available |
| **pH:** | Not available | **Relative density:** | No data available |
| **Melting/freezing point:** | No data available | **Solubility(ies):** | No data available |
| **Initial boiling point and boiling range:** | No data available | **Partition coefficient: n-octanol/water:** | Not available |
| **Flash point:** | > 200°F (93°C) | **Auto-ignition temperature:** | No data available |
| **Evaporation rate:** | No data available | **Decomposition temperature:** | No data available |
| **Flammability (solid, gas):** | Not applicable | **Viscosity:** | No data available |

| | | | |
|---|---|---|---|
| **Explosive Properties:** | No data available | **Oxidizing Properties:** | Not an oxidizer |

**9.2 Other Information:** None available.

## 10. STABILITY AND REACTIVITY

**10.1 Reactivity:** None known.

**10.2 Chemical Stability:** Stable under normal storage and handling conditions. Unstable if heated.

**10.3 Possibility of Hazardous Reactions:** Polymerization can occur. Conditions leading to polymerization are excessive heat, oxygen-free atmosphere inhibitor depletion (due to excessive aging), direct sunlight or ultraviolet light, and contamination with polymerization catalysts or incompatible materials.

**10.4 Conditions to Avoid:** Direct sunlight.

**10.5 Incompatible materials:** Avoid contact with oxidizing agents, reducing agents, inert gas (oxygen free atmosphere), oxygen scavengers, and peroxides.

**10.6 Hazardous Decomposition Products:** Carbon monoxide, carbon dioxide, methacrylates, and irritating smoke.

## 11. TOXICOLOGICAL INFORMATION

**11.1 Information on Toxicological Effects:**

**Potential Health Effects:**
Eyes: May cause severe irritation with redness and tearing. May cause permanent eye damage.
Skin: May cause mild irritation. Prolonged or repeated exposure may cause dermatitis. May cause allergic skin reaction (sensitization).
Ingestion: May be harmful if swallowed.
Inhalation: None expected during normal use.

**Chronic Health Effects:** None expected during normal use.

**Irritation:**
Organic acrylate monomer is severely irritating to eyes and non-irritating to skin.

**Corrosivity:** Organic acrylate monomer is corrosive to eyes. Methacrylic Acid is corrosive to eyes and skin.

**Sensitization:** Photoinitiator: Sensitizing in Mouse local lymph node assay. Individuals with sensitivity to methacrylates may develop an allergic reaction. Organic acrylate monomer and Organic methacrylate monomer are sensitizing in guinea pig maximization tests.

**Carcinogenicity:** None of the components of this product are known to be listed as carcinogens by IARC, NTP, OSHA, or the EU CLP.

**Mutagenicity:** No data available.

**Acute Toxicity Data:**
Urethane Methacrylate: No toxicity data available
Organic acrylate monomer: Oral rat LD50 - >2000 mg/kg

Photoinitiator: Oral rat LD50 - >5000 mg/kg; Skin rat LD50- >2000 mg/kg
Methacrylic Acid: Skin rat LD50- 500 mg/kg

**Reproductive Toxicity Data:**
Photoinitiator: Animal studies show skeletal malformations in offspring and damage to the testes in dosed animals.

Organic acrylate monomer: Animal studies show no adverse effects on fertility or development of offspring.

**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 Ecotoxicity:**
Urethane Methacrylate Ester: 72 hr ErC50 Desmodesmus subspicatus (green algae) - 2.28 mg/L; NOEC Daphni magna – 0.291 mg/L
Organic methacrylate monomer: 96 hr LC50 Leuciscus idus – 10 mg/L; 48 hr EC50 Daphnia magna – 1.21 mg/L
Photoinitiator: 48 hr LC50 Oryzias latipes - 6.53 mg/L; 48 hr EC50 Daphnia magna - 3.53 mg/L
Organic acrylate monomer: 48 hr LC50 Leuciscus idus - 11.5 mg/L; 48 hr EC50 Daphnia magna – 19.5 mg/L
This product is classified as toxic to the aquatic environment with long-term adverse effects. Releases to the environment should be avoided

**12.2 Persistence and Degradability:** Photoinitiator: Not readily biodegradable- <20% in 28 days.
Organic acrylate monomer: Not readily biodegradable – 35.1% 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:** 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 | None |
| **ADR/ RID** | UN3082 | Environmentally Hazardous Substance, Liquid, n.o.s. (Organic methacrylate monomer and Organic acrylate | 9 | III | Yes |

| | | | | | |
|---|---|---|---|---|---|
| | | monomer) | | | |
| **IMDG** | UN3082 | Environmentally Hazardous Substance, Liquid, n.o.s. (Organic methacrylate monomer and Organic acrylate monomer) | 9 | III | Marine Pollutant |
| **IATA/ ICAO** | UN3082 | Environmentally Hazardous Substance, Liquid, n.o.s. (Organic methacrylate monomer and Organic acrylate monomer) | 9 | III | Yes |

**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.

**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 Water Act.

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

**SARA Section 311/312 (40 CFR 370) Hazard Categories:** Refer to Section 2 for OSHA Hazard Classification.

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

**State Regulations**

U.S. State Regulations California Proposition 65:

**WARNING:** This product can expose you to chemicals including, Toluene, which is known to the State of California to cause cancer and birth defects or 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.

**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.

**Japanese Existing and New 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: 1 Physical Hazard: 1

Full Text of Hazard Statements and Abbreviations used In Section 3:
Acute Tox. 3 Acute Toxicity Category 3
Acute Tox. 4 Acute Toxicity Catgory 4
Aq. Chronic 2 Aquatic Chronic Toxicity Category 2
Eye Dam. 1 Eye Damage Category 1
Repr. 2 Reproductive Toxicity Category 2
Skin Corr. 1A Skin Corrosion 1A
Skin Sens. 1B Skin Sensitizer Category 1B
STOT SE 3 Specific Target Organ Toxicity Single Exposure
H302 Harmful if swallowed.
H311 Toxic in contact with skin.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H335 May cause respiratory irritation.
H361df Suspected of damaging fertility or the unborn child.
H411 Toxic to aquatic life with long lasting effects.

Supersedes: N/A
Date Updated: 21 June 2019
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.