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: 23 May 2006
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Revision Number: 3

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

1.1 Product Identifier:

Trade Name (as labeled): **Lucitone Digital Fuse™ Step 3 – 3D Sealer**

Part/Item Number: **906195**

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

Recommended Use: **Used as a bonding aid for denture teeth**

Restrictions on Use: **For Professional Use Only**

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name: **Dentsply Sirona**

Manufacturer/Supplier Address: **1301 Smile Way**
York, PA 17404

Manufacturer/Supplier Telephone Number: **717-845-7511 (Product Information)**

Email address: **Prosthetics-SDS@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
Skin Irritant Category 2 (H315) Skin Sensitization Category 1 (H317) Eye Damage Category 1 (H318) Toxic to Reproduction Category 2 (H361)	Aquatic Acute Toxicity Category 3 (H402) Aquatic Chronic Toxicity Category 3 (H412)	Flammable Liquid Category 2 (H225)

2.2 Label Elements:

Signal Word: Danger

Contains: Methyl Methacrylate and (2,4,6-trioxo-1,3,5-triazine-1,3,5(2H,4H,6H)-triyl)tri-2,1-ethanediyl triacrylate

Hazard Phrases	Precautionary Phrases
H225 Highly flammable liquid and vapor. H315 Causes skin irritation. H317 May cause an allergic skin reaction. H318 Causes serious eye damage. H361 Suspected of damaging fertility or the unborn child. 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, hot surfaces, sparks, open flames, and other ignition sources. No smoking. P233 Keep container tightly closed. P240 Ground or bond container and receiving equipment. P241 Use explosion-proof electrical, ventilating, and lighting equipment. P242 Use only non-sparking tools. P243 Take action to prevent static discharge. P261 Avoid breathing vapors. P264 Wash thoroughly after handling. P272 Contaminated work clothing must not be allowed out of the workplace. P273 Avoid release to the environment. P280 Wear protective gloves and eye protection. P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. P333+P313 If skin irritation or rash occurs: Get medical attention. P363 Wash contaminated clothing before reuse. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 Immediately call a POISON CENTER or doctor. P308+P313 IF exposed or concerned: Get medical attention. P370+P378 In case of fire: Use carbon dioxide, foam, water spray or water fog to extinguish. P403+P235 Store in a well-ventilated place. Keep cool. 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 %

Methyl Methacrylate	80-62-6	201-297-1 /	Flam. Liq. 2 (H225) Skin Irrit. 2 (H315) Skin Sens. 1 (H317) STOT SE 3 (H335)	40-50
(2,4,6-trioxo-1,3,5-triazine-1,3,5(2H,4H,6H)-triyl)tri-2,1-ethanediyl triacrylate	40220-08-4	254-843-6 /	Eye Dam. 1 (H318) Skin Sens. 1 (H317) Aquatic Acute 3 (H402) Aquatic Chronic 3 (H412)	30 - 35
diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	75980-60-8	278-355-8 /	Skin Sens. 1B (H317) Repro 2 (H361) Aquatic Acute 2 (H401) Aquatic Chronic 2 (H411)	1-4

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 for 20 minutes. Get immediate medical attention.
Skin	None required for cured product. In case of contact with uncured product, wash skin thoroughly with soap and water for several minutes. Get medical attention if irritation or rash occurs. Remove and launder clothing before re-use.
Inhalation	No first aid is generally required. If irritation is experience, remove victim to fresh air and keep comfortable for breathing. Get medical attention if irritation or symptoms persist.
Ingestion	If small quantities are swallowed, rinse out mouth with water. Do not induce vomiting unless directed to do so by a medical professional. Get medical attention if symptoms develop or if you feel unwell.

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

Contact with uncured resin can cause serious eye irritation with possible damage. Contact with uncured resin causes skin irritation and may cause allergic skin reaction. Individuals with sensitivity to methacrylates may develop an allergic reaction when exposed to this product. This product contains a chemical that is suspected of damaging fertility or the unborn child.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:

Immediate medical attention may be required for direct eye contact.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media:	Use carbon dioxide, foam, or dry chemical.

5.2 Special Hazards Arising from the Substance or Mixture:

Highly flammable liquid and vapor. Vapors are heavier than air and may travel to ignition source and flash back. Emits toxic fumes under fire conditions. Closed containers may explode due to pressure build up when exposed to extreme heat. Decomposition may release carbon monoxide, carbon dioxide, methyl methacrylate, and irritating smoke.

5.3 Advice for Fire-Fighters:

Fire Fighting Procedures/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. Fight fire from a safe distance of protected location. Use water to cool fire-exposed containers. Contain water used in firefighting from entering sewers or natural waterways.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Evacuate spill area and keep unprotected personnel away. Remove all ignition sources such as open flames, spark producing equipment, pilot lights, etc. Use non-sparking tools and equipment. Avoid breathing vapors. Ventilate area with explosion proof equipment. Avoid contact with skin, eyes or clothing. Wear appropriate protective clothing as described in Section 8.

6.2 Environmental Precautions:

Avoid releases to the environment. Report spills and releases as required to appropriate authorities.

6.3 Methods and Material for Containment and Cleaning up:

Contain and collect using an inert absorbent material and place in appropriate containers for disposal. Clean spill site with water. Use non-sparking tools.

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 as described in Section 8. Avoid breathing vapors. Use with adequate ventilation. Wash thoroughly with soap and water after handling. Keep product away from heat, sparks, flames and all other sources of ignition. No smoking in storage or use areas. Use with non-sparking tools and explosion proof equipment. Electrically bond and ground containers for transfer. 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 oxidizers and other incompatible materials. Do not store in direct sunlight. Prevent moisture contact. 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:	
Methyl Methacrylate	50 ppm TWA, 100 ppm STEL ACGIH TLV (DSEN) 100 ppm TWA OSHA PEL 50 ppm TWA, 100 ppm STEL DFG MAK 50 ppm TWA, 100 ppm STEL UK WEL 50 ppm TWA, 100 ppm STEL Belgium OEL 50 ppm TWA, 100 ppm STEL Belgium OEL 50 ppm TWA, 100 ppm STEL EU OEL
2,4,6-trioxo-1,3,5-triazine-1,3,5(2H,4H,6H)-triyl)tri-2,1-ethanediyl triacrylate	None Established
diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	None Established
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. Use explosion proof electrical equipment and wiring where required.

Individual Protection Measures (PPE):

Specific Eye/face Protection: Wear safety glasses when the possibility exists for eye contact.

Specific Skin Protection: Wear impervious gloves to avoid skin contact. Wear impervious clothing as needed to avoid contact with this product.

Specific Respiratory Protection: None required with adequate ventilation. If the occupational exposure limits are exceeded, an approved respirator with applicable 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:	Yellow, low viscosity liquid	**Explosive limits:**	**LEL:** 2.1% **UEL:** 12.5%
Odor:	Characteristic acrylate odor	**Vapor pressure (mmHg):**	≤ 35 mmHg @ 68°F (20°C)
Odor threshold:	0.21 ppm (methyl methacrylate)	**Vapor density: (Air=1)**	3.45
pH:	Not available	**Relative density:**	1.1 @ 68°F (20°C)
Melting/freezing point:	Not available	**Solubility(ies):**	Water: Negligible
Initial boiling point and boiling range:	212°F (100°C)	**Partition coefficient: n-octanol/water:**	Not available

Flash point:	55°F (13°C) TOC	**Auto-ignition temperature:**	815°F (435°C)
Evaporation rate: (n-BuAc = 1)	Not available	**Decomposition temperature:**	Not available
Flammability (solid, gas):	Flammable	**Viscosity:**	Not available
Explosive Properties:	Vapors may form explosive concentrations in confined areas	**Oxidizing Properties:**	Not an oxidizer

9.2 Other Information: None available.

10. STABILITY AND REACTIVITY

10.1 Reactivity: Polymerization can occur.

10.2 Chemical Stability: Stable under normal storage and handling conditions.

10.3 Possibility of Hazardous Reactions: Can occur if large quantities are involved. Not likely to occur for quantities used in dental laboratories.

10.4 Conditions to Avoid: Heat, sparks, open flame and other ignition sources, elevated temperatures, direct sunlight.

10.5 Incompatible materials: Substance is incompatible with strong oxidizing agents, strong reducing agents, free radical initiators, inert gases and oxygen scavengers.

10.6 Hazardous Decomposition Products: Carbon monoxide, irritating and toxic fumes and gases, carbon dioxide.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:
Eyes: Direct eye contact with uncured resin causes severe irritation with possible damage.
Skin: Uncured resin causes skin irritation. May cause allergic skin reaction in sensitized individuals. Contact with cured material will not cause skin irritation.
Ingestion: Ingestion is unlikely due to form. Small amounts are not anticipated to cause adverse effects. Large quantities may cause gastrointestinal disturbances.
Inhalation: Not expected to cause respiratory tract irritation based on product test data.

Chronic Health Effects: Prolonged or repeated overexposure may cause skin irritation or sensitization in some individuals.

Irritation: Methyl Methacrylate: Moderately to slightly irritating to rabbit skin. Slightly to non-irritating to rabbit eyes. (2,4,6-trioxo-1,3,5-triazine-1,3,5(2H,4H,6H)-triyl)tri-2,1-ethanediyl triacrylate causes severe eye irritation and possible damage.

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

Sensitization: Methyl Methacrylate: Sensitizing in a Mouse local lymphnode assay. 2,4,6-trioxo-1,3,5-triazine-1,3,5(2H,4H,6H)-triyl)tri-2,1-ethanediyl triacrylate: Is classified as a skin sensitizer.

Carcinogenicity: Methyl methacrylate: The results of a 2-year inhalation studies conducted for NTP showed no evidence of carcinogenicity of methyl methacrylate for male rats exposed at 500 or 1,000 ppm and female rats exposed at 250, 500 or 1,000 ppm. In another study, no increase was seen in the number or type of tumors in either rats or hamsters from a chronic inhalation study. No carcinogenic activity was also reported in a chronic oral study. However, acute oral exposure studies

and structure-activity relationship comparisons with other acrylates suggest that the introduction of a methyl group to the acrylate moiety (e.g., EC to MMA) negates carcinogenic activity. None of the other components of this product are listed as carcinogens by OSHA, IARC, NTP, or the EU CLP.

Mutagenicity: Methyl Methacrylate: Negative in AMES test, positive and negative in in-vitro studies. Negative in vivo studies.

Aspiration Hazard: Not an aspiration hazard

Acute Toxicity Data:

Methyl Methacrylate: Oral rat LD50- 7800 mg/kg; Inhalation rat LC50- 29.8 mg/L/ 4hr (7093 ppm/4 hr); Skin rabbit LD50- >5000 mg/kg

2,4,6-trioxo-1,3,5-triazine-1,3,5(2H,4H,6H)-triyl)tri-2,1-ethanediyl triacrylate: Oral rat LD0 > 2000 mg/kg

Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide: Oral rat LD50 > 5000 mg/kg, dermal rat LD50 > 2000 mg/kg

Reproductive Toxicity Data: Methyl Methacrylate: In a study in rats, there were no developmental effects, although there were decreases in maternal body weight following inhalation of concentrations up to 8,315 mg/m^3. There was no reduction in fertility in a dominant lethal assay in mice exposed to this compound at concentrations up to 36,900 mg/m^3 and no adverse effects on reproductive organs in repeated dose studies conducted to date.

Specific Target Organ Toxicity Single Exposure (STOT-SE): Methyl Methacrylate: In an inhalation study with dogs, a 2000 ppm dose showed a drop in arterial blood pressure and GI motor activities. The lethal oral dose for methyl methacrylate is 6 to 9 g/kg in lab animals. Poisoned animals exhibit respiratory depression, and coma; also irritation of skin, eyes and respiratory tract.

Specific Target Organ Toxicity Repeated Exposure (STOT-RE): Methyl Methacrylate: Impairment of locomotor activity and learning and behavioral effects on the brain were observed in rats exposed orally to 500 mg/kg by weight per day for 21 days.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:
Methyl Methacrylate: LC50 Fathead minnow- 130 mg/L/96h ; 48h EC50 Algae- 170 mg/L
2,4,6-trioxo-1,3,5-triazine-1,3,5(2H,4H,6H)-triyl)tri-2,1-ethanediyl triacrylate: Daphnia magna EC50 158.3 mg/L/48h
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide: Oryzias latipes LC50 6.53 mg/L/48h

This product is harmful to aquatic life with long lasting effects. Releases to the environment should be avoided.

12.2 Persistence and Degradability: Methyl mathacrylate is readily biodegradable - 88% after 28 days.

12.3 Bio-accumulative Potential: The potential for bioaccumulate is expected to be low for methyl methacrylate.

12.4 Mobility in Soil: Methyl methacrylate is expected to have very high to high mobility in soil.

12.5 Results of PBT and vPvB Assessment: Not applicable

12.6 Other Adverse Effects: None

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	UN1247	Methyl Methacrylate Monomer, Inhibited	3	II	Not applicable
ADR/RID	UN1247	Methyl Methacrylate Monomer, Inhibited	3	II	Not applicable
IMDG	UN1247	Methyl Methacrylate Monomer, Inhibited	3	II	Not applicable
IATA/ICAO	UN1247	Methyl Methacrylate Monomer, Inhibited	3	II	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): Releases above the RQ of 2,000 lbs. (based on the RQ for methyl methacrylate of 1,000 lbs. present at 50%) 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.

Clean Water Act (CWA): This material is not regulated under the Clean Water Act.

Clean Air Act (CAA): Methyl methacrylate 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: See OSHA Hazard Classification in Section 2.

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

Components	C.A.S. #	WT %
Methyl Methacrylate	80-62-6	40-50%

State Regulations

California:

WARNING: This product can expose you to chemicals including Methanol, which is known to the State of California to cause 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.

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: 3 Flammability: 3 Physical Hazard: 1

Full Text of Hazard Statements and Abbreviations used In Section 3:
Aquatic Acute 2 Aquatic Acute Toxicity Category 2
Aquatic Acute 3 Aquatic Acute Toxicity Category 3
Aquatic Chronic 2 Aquatic Chronic Toxicity Category 2
Aquatic Chronic 3 Aquatic Chronic Toxicity Category 3
Eye Dam. 1 – Eye Damage Category 1
Flam. Liq. 2 - Flammable Liquid Category 2
Repro 2 - Reproductive Hazard Category 2
Skin Irrit. 2 - Skin Irritant Category 2
Skin Sens. 1 - Skin Sensitization Category 1
STOT SE 3 – Specific Target Organ Toxicity Single Exposure Category 3
H225 Highly flammable liquid and vapor.
H315 Causes skin irritation.
H318 Causes serious eye damage
H317 May cause an allergic skin reaction.
H335 May cause respiratory irritation.
H361 Suspected of damaging fertility or the unborn child.
H401 Toxic to aquatic life.
H402 Harmful to aquatic life.
H411 Toxic to aquatic life with long lasting effects.
H412 Harmful to aquatic life with long lasting effects.

Supersedes: 27 September 2019
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Revision Summary: Update logo, legal manufacturer address, and email

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, ECHA REACH Registration Website,

Country websites for occupational exposure limits.