

DENTSPLY International

Prosthetics

Safety Data Sheet

Safety Data Sheet conforms to Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010, US 29CFR1910.1200, Canada Hazardous Products Regulation

Date Issued: 23 May 2019
Document Number: 670
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Revision Number: 1

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

1.1 Product Identifier:

Trade Name (as labeled): Lucitone Digital Fuse™ Step 1 - 3D Tooth Conditioning Agent
Part/Item Number: 906185

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

Recommended Use: Aids in the Adhesion of denture teeth to denture resin
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 Irritant Category 2 (H319) Reproductive Toxicity Category 2 (H360Df) Skin Irritant Category 2 (H315) Skin Sensitization Category 1 (H317) Specific Target Organ Toxicity-Single Exposure Category 3 (H336)	Not Hazardous	Flammable Liquid Category 2 (H225)

2.2 Label Elements:



Signal Word: Danger

Contains: Methyl Acetate, Cyclohexane Diol Dimethylacrylate, Diphenyl(2,4,6,-trimethylbenzoyl)phosphine oxide

Hazard Phrases	Precautionary Phrases
<p>H225 Highly flammable liquid and vapor. H315 Causes skin irritation. H319 Causes serious eye irritation. H317 May cause an allergic skin reaction. H336 May cause drowsiness or dizziness. H360Df May damage the unborn child through ingestion. Suspected of damaging fertility. EUH066 Repeated exposure may cause skin dryness or cracking.</p>	<p>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 precautionary measures against static discharge. P261 Avoid breathing mist, vapors or spray. P264 Wash thoroughly after handling. P271 Use only outdoors or in a well-ventilated area. P272 Contaminated work clothing should not be allowed out of the workplace. P280 Wear protective gloves, protective clothing, 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. 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. P362+P364 Take off contaminated clothing and wash it before reuse. P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P312 Call a POISON CENTER or doctor if you feel unwell. 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.</p>

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 Acetate	79-20-9	201-185-2 /	Flam. Liq. 2, H225 Eye Irrit. 2A, H319 STOT SE 3, H336 EUH066	50-80
Cyclohexane Diol Dimethylacrylate	67905-41-3	267-661-7 /	Eye Irrit. 2A, H319 Skin Irrit. 2, H315 Skin Sens. 1B, H317	10-20
1, 6 -Hexanediol Diacrylate	13048-33-4	235-921-9 /	Eye Irrit. 2A, H319 Skin Irrit. 2, H315 Skin Sens. 1, H317 Aq. Chronic 3, H412	5-15
Tetrahydrofurfuryl Methacrylate	2455-24-5	219-529-5 /	Skin Sens. 1, H317 Repr. 1B, H360Df Aq. Chronic 3, H412	1-10
Diphenyl(2,4,6,- trimethylbenzoyl)phosphine oxide	75980-60-8	278-355-8 /	Skin Sens. 1B, H317 Repr. 2, H361 Aq. Acute 2, H401 Aq. Chronic 2, H411	<0.5
Methacrylic acid	79-41-4	201-204-4 /	Acute Tox. 3, H311 Acute Tox. 4, H302, H332 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 3, H335	<0.2

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 for several minutes, while holding the eyelids apart. Get medical attention if irritation persists.
Skin	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	Remove victim to fresh air. Give artificial respiration if needed. If breathing is difficult, oxygen should be administered by qualified personnel. Get medical attention if irritation or symptoms of exposure 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 you feel unwell.

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

May cause eye, skin, and respiratory tract irritation. Prolonged or repeated contact may cause allergic skin reaction (skin rash). Inhalation of vapors may cause dizziness, headache, and other central nervous system effects. This product contains a component that is suspected of damaging fertility based on animal studies.

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 spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special Hazards Arising from the Substance or Mixture:

This product is a highly flammable liquid and forms explosive mixtures with air. Vapors are heavier than air and will travel along surfaces to remote ignition sources and flash back. Closed containers may explode due to pressure build up when exposed to extreme heat. Decomposition may release carbon monoxide, carbon dioxide, and acrid 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 exposed containers, structures, and disperse flammable vapors.

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 or mists. 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:

Report releases as required by local and national authorities.

6.3 Methods and Material for Containment and Cleaning up:

Contain and collect using inert absorbent materials and place in appropriate containers for disposal. Use non-sparking tools and equipment. If spill has not ignited, use water spray to disperse the vapors and protected personnel attempting to stop leak.

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 mists or 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 cut, drill, grind or weld on or near containers, even empty 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 accordance with regulations for the storage of flammable liquids. Store in a cool, dry, well-ventilated area away from heat, direct sunlight and all sources of ignition. Store away from oxidizers 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:**

Methyl Acetate	200 ppm TWA, 250 ppm STEL ACGIH TLV 200 ppm TWA OSHA PEL 100 ppm TWA, 400 ppm STEL DFG MAK 200 ppm TWA, 250 ppm STEL UK WEL 200 ppm TWA, 250 ppm STEL Belgium OEL
Cyclohexane Diol Dimethylacrylate	None Established
1, 6 -Hexanediol Diacrylate	1 mg/m ³ TWA AIHA WEEL
Tetrahydrofurfuryl Methacrylate	None Established
Diphenyl(2,4,6,-trimethylbenzoyl)phosphine oxide	None Established
Methacrylic acid	20 ppm TWA ACGIH TLV 5 ppm TWA, 10 ppm STEL DFG MAK 20 ppm TWA, 40 STEL UK WEL 20 ppm 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 exposure levels below the occupational exposure limits. Use explosion proof electrical equipment and wiring where required.

Individual Protection Measures (PPE):

Specific Eye/face Protection: Chemical safety goggles are recommended.

Specific Skin Protection: Wear impervious gloves such as nitrile gloves. Do not use PVC or latex gloves.

Specific Respiratory Protection: None should be needed for normal use. If the exposure limits are exceeded an approved organic vapor 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 translucent liquid	Explosive limits:	LEL: 3.1% (Methyl acetate) UEL: 16% (Methyl acetate)
Odor:	Fruity odor	Vapor pressure (mmHg):	17 mmHg@ 20°C (68°F)
Odor threshold:	Not determined	Vapor density: (Air=1)	2.6
pH:	6.8-7.2	Relative density:	0.95 @ 20°C (68°F)
Melting/freezing point:	-99°C (-146°F)	Solubility(ies):	Appreciable
Initial boiling point and boiling range:	58°C (136°F)	Partition coefficient: n-octanol/water:	Not available
Flash point:	-13°C (8.6°F)	Auto-ignition temperature:	501°C (934°F)
Evaporation rate: (n-BuAc = 1)	5.3	Decomposition temperature:	Not available
Flammability (solid, gas):	Not applicable	Viscosity:	Not available
Explosive Properties:	Heated containers may prove explosive due to pressure.	Oxidizing Properties:	None

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.

10.3 Possibility of Hazardous Reactions: If inhibitors are depleted, product can polymerize, raising temperature and pressure, possibly rupturing container.

10.4 Conditions to Avoid: Keep away from heat, sparks, and flames. Avoid excessive heat, exposure to sunlight and ultraviolet light.

10.5 Incompatible materials: Avoid oxidizing agents, strong reducers and free radical initiators.

10.6 Hazardous Decomposition Products: Thermal decomposition may produce carbon monoxide, carbon dioxide, and acrid smoke.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: Vapors or mists may cause irritation with redness, tearing and stinging. Direct contact with liquid may cause severe irritation.

Skin: May cause moderate skin irritation. May cause allergic skin reaction (skin sensitization).

Ingestion: Ingestion may cause mucous membrane and gastrointestinal irritation.

Inhalation: Inhalation of vapors or mists may cause mucous membrane and respiratory, dizziness and drowsiness. High vapor concentrations may cause central nervous system depression, narcosis and unconsciousness.

Chronic Health Effects: Prolonged occupational overexposure may cause defatting of the skin and dermatitis. Methyl acetate may hydrolyze in the body producing methanol. The systemic effects of methanol poisoning such as blurred vision, changes in color perception, blindness, kidney or liver damage may occur.

Irritation: This product is classified as an eye and skin irritant based on the components.

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

Sensitization: 1, 6 -Hexanediol Diacrylate: Sensitizing in Guinea Pig Maximisation Test. Diphenyl (2,4,6 trimethylbenzoyl) phosphine oxide: Sensitizing in Mouse local lymphnode assay.

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

Mutagenicity: Methyl Acetate: Methyl acetate was tested for mutagenicity with the strains TA 100, TA 1535, TA 1537, TA 1538, TA 98 of Salmonella typhimurium and Escherichia coli WP2uvrA. The results were negative and it was concluded that Methyl acetate is not mutagenic in these bacterial test systems either with or without exogenous metabolic activation.

Acute Toxicity Data:

Methyl Acetate: Oral rat LD50 - >5000 mg/kg, Skin rabbit LD50 - >5000 mg/kg

Cyclohexane Diol Dimethylacrylate: No toxicity data available

1, 6 -Hexanediol Diacrylate: Oral rat LD50 – 5000 mg/kg; Skin rabbit LD50 – 3600 mg/kg

Tetrahydrofurfuryl Methacrylate: No toxicity data available

Diphenyl(2,4,6,-trimethylbenzoyl)phosphine oxide: No toxicity data available

Methacrylic acid: Oral rat LD50- 1320 mg/kg, Inhalation rat LC50- 7.1 mg/L/4hr, Skin rabbit LD50- 500-1000 mg/kg

Reproductive Toxicity Data: 1, 6 -Hexanediol Diacrylate: Animal studies using rats revealed that some acrylates and methacrylates are embryotoxic. The doses of monomers used in the animal studies, however, were much higher than concentrations likely encountered by workers. In a rat study where maternal toxicity and developmental toxicity were studied, the maternal toxicity resulted in a NOAEL of 250 mg/kg by weight per day (actual dose received) and the developmental toxicity resulted in a NOAEL of 750 mg/kg by weight per day (actual dose received). Diphenyl (2,4,6-trimethylbenzoyl)phosphine oxide: Animal studies suggest a fertility impairing effect. Testicular atrophy was seen in all male rats dosed at 750 mg/kg/day.

Specific Target Organ Toxicity Single Exposure (STOT-SE): No data available.

Specific Target Organ Toxicity Repeated Exposure (STOT-RE): Methyl Acetate: Groups of 10 male and 10 female Sprague Dawley rats received methyl acetate by nose-only inhalation exposure at concentrations of 0, 75, 350 and 2000 ppm for a period of 28 days (6 hours per day, 5 days per week). Repeated exposure of Sprague Dawley rats to methyl acetate at the concentration of 2000 ppm caused impaired body weight gain, decreased food consumption and pathological changes of the olfactory epithelium. The toxicological relevance of the clinical chemistry findings remains unclear. Adrenal weights were increased in both sexes, possible reflecting stress of the animals caused by exposure to an irritant concentration of the test compound. At the concentration of 350 ppm, slight increases in adrenal weights and slight decreases in thymus weights were observed in females. No Observed Adverse Effect Level (NOAEL) is 350 ppm methyl acetate for male and female Sprague-Dawley rats, equivalent to a concentration of 1057 mg/m³ air. Diphenyl(2,4,6-

trimethylbenzoyl)phosphine oxide: May cause damage to the testes after repeated ingestion of high doses, in animal studies.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

Methyl Acetate: 96 hr LC50 Fathead minnow – 320 mg/L (flow through); 96 hr LC50 Zebrafish – 250-350 mg/L (static); 48 hr EC50 Daphnia magna – 1026.7 mg/L

1, 6 -Hexanediol Diacrylate: 96 hr LC50 Ide fish- 4.6-10 mg/L, 48 hr EC50 Daphnia magna- 2.6 mg/L

Tetrahydrofurfuryl Methacrylate: 96 hr LC50 Fathead minnow – 34.7 g/L

Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide: 48 hr LC50 Oryzias latipes- 6.53 mg/L; 48 hr EC50 Daphnia magna- 3.53 mg/L

12.2 Persistence and Degradability: Methyl Acetate: readily biodegradable - >70% after 28 days. Diphenyl (2,4,6-trimethylbenzoyl)phosphine oxide: Not readily biodegradable- <20% 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 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	UN1231	Methyl Acetate Solution	3	II	No
ADR/RID	UN1231	Methyl Acetate Solution	3	II	No
IMDG	UN1231	Methyl Acetate Solution	3	II	No
IATA/ICAO	UN1231	Methyl Acetate Solution	3	II	No

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 other states have more stringent release reporting regulations. Report all spills in accordance with local, state, and federal 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 Air Act.

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

SARA Section 311/312 (40 CFR 370) Hazard Categories: Acute Health, 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: **WARNING:** This product can expose you to chemicals including which are Methanol, Toluene, and Tetrahydrofurfuryl Methacrylate, which are 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.

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: 3 Physical Hazard: 1

*Chronic Health Hazard

Full Text of Hazard Statements and Abbreviations used In Section 3:

Acute Tox. 3 Acute Toxicity Category 3

Acute Tox. 4 Acute Toxicity Category 4

Aq. Chronic 2 Aquatic Chronic Toxicity Category 2

Aq. Chronic 3 Aquatic Chronic Toxicity Category 3

Eye Dam. 1 Eye Damage Category 1

Eye Irrit. 2 Eye Irritant Category 2

Flam. Liq. 2 Flammable Liquid Category 2

Flam. Liq. 4 Flammable Liquid Category 4

Repr. 1B Reproductive Toxicity Category 1B

Skin Corr. 1A Skin Corrosion Category 1A

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.

H227 Combustible liquid

H302 Harmful if swallowed.

H311 Toxic in contact with skin.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H335 May cause respiratory irritation.

H336 May cause drowsiness or dizziness.

H360Df May damage the unborn child through ingestion. Suspected of damaging fertility.

H401 Toxic to aquatic life.

H411 Toxic to aquatic life with long lasting effects.

H412 Harmful to aquatic life with long lasting effects.

Supersedes: 23 May 2019

Date Updated: 8 August 2019

Revision Summary: Updated Section 2.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, ECHA Registered Substances, C&L Inventory, Country websites for occupational exposure limits.