Safety Data Sheet

Safety Data Sheet conforms to Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 2020/878, US 29CFR1910.1200, Canada Hazardous Products Regulation

Date Issued: 14 October 2021
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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 IPN™ 3D Premium Tooth**

Part/Item Numbers: **906381, 906382, 906383, 906384, 906385, 906386, 906387, 906388, 906389, 906390, 906391, 906392, 906393, 906394, 906395, 906396, 906397, 906398**

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

Recommended Use: Resin for printed 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. HAZARD(s) IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS Classification:		
Health	**Environmental**	**Physical**
Skin Irritation Category 2 (H315) Skin Sensitization Category 1 (H317) Eye Irritation Category 2 (H319) Toxic to Reproduction Category 1B (H360)	Hazardous to the Aquatic Environment – Long-Term Hazard Category 3 (H412)	Not Hazardous

OSHA Specific Hazards: None

2.2 Label Elements:

Signal Word: Danger

Contains: Urethane acrylate, Ethylene Glycol Dimethacrylate (EGDMA), Diphenyl (2,4,6-trimethylbenzoyl) phosphine oxide

Hazard Phrases	Precautionary Phrases
H315 Causes skin irritation. H317 May cause an allergic skin reaction H319 Causes serious eye irritation. H360 May damage 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. P261 Avoid breathing mist, vapors or spray. P264 Wash thoroughly after handling. P272 Contaminated work clothing must not be allowed out of the workplace. P273 Avoid release to the environment. P302 + P352 IF ON SKIN: Wash with plenty of soap and water. 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. P337 + P313 If eye irritation persists: Get medical attention. P308 + P313 IF exposed or concerned: Get medical attention. P280 Wear protective gloves, and eye protection. P405 Store locked up. P501 Dispose of contents and container in accordance with local and national regulations.

2.3 Other Hazards: None

3. COMPOSITION AND INFORMATION ON INGREDIENTS

3.1 Mixture:

Hazardous Components	C.A.S. #	EINECS # / REACH Registration #	Classification	WT %
Urethane Methacrylate	Proprietary	Proprietary	Skin Irrit. 2 (H315) Skin Sens. 1 (H317) Eye Irrit. 2 (H319)	50-60
3, 3, 5 trimethyl cyclohexanol - Alkyl methacrylate	7779-31-9	231-927-0/	Skin Irrit. 2 (H315) Skin Sens. 1B (H317) Aq. Chronic 2 (H411)	10-20
Ethylene Glycol Alkyl Dimethacrylate	97-90-5	202-617-2/	Skin Sens. 1B (H317) STOT SE 3 (H335) Aq. Chronic 3 (H412)	5-15
Propoxylated bisphenol A urethane dimethacrylate oligomer	Proprietary	Proprietary	Skin Irrit. 2 (H315) Skin Sens. 1 (H317) Eye Irrit. 2 (H319)	5-10
Diphenyl (2,4,6-trimethylbenzoyl) phosphine oxide	75980-60-8	278-355-8/	Skin Sens. 1B (H317) Repro Tox 1B (H360) Aq. Chronic 2 (H411)	1-5
Carbon Black*	1333-86-4	215-609-9/	Carc. 2 (H351)	< 0.2
Titanium Dioxide*	13463-67-7	236-675-5 /	Carc. 2 (H351)	< 0.2

Butylated Hydroxytoluene	128-37-0	204-881-4/	Eye Irrit. 2 (H319) STOT SE 3 (H336) Aq. Acute 1 (H400) Aq. Chronic 1 (H410)	0.1

* Titanium dioxide and Carbon black are incorporated into a viscous liquid and is not present as a respirable dust. There is no exposure to respirable titanium dioxide or carbon black dust in the normal use of this product.

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:	
Routes of Exposure	**First Aid Instructions**
Eye	Flush eyes with large quantities of water for at least 15 minutes, holding the eyelids apart. Get medical attention if irritation persists.
Skin	Remove clothing. Wash skin thoroughly for several minutes 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	Rinse out mouth with water. Do not induce vomiting unless directed to do so by a medical professional. Never give anything by mouth to an unconscious or drowsy person. Seek medical attention if large amounts are ingested.
4.2 Most Important Symptoms and Effects, Both Acute and Delayed:	
Causes serious eye irritation. Causes 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. Inhalation may cause irritation to upper respiratory tract. May damage fertility or the unborn child.	
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, foam, carbon dioxide, water spray or dry chemical.
Fire Fighting Procedures:	Cool fire exposed containers and structures with water.
5.2 Special Hazards Arising from the Substance or Mixture:	
Will burn under fire conditions. May polymerize if exposed to high temperatures. Thermal decomposition may release carbon monoxide, carbon dioxide, methacrylates, and irritating smoke.	
5.3 Advice for Fire-Fighters:	
Fire Fighting Procedures/Precautions for Fire Fighters:	Cool fire exposed containers with water spray. Firefighters should wear full emergency equipment and approved positive pressure self-containing breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:
Ventilate the area. Avoid contact with skin, eyes or clothing. Avoid breathing vapors, mist, or spray. Wear appropriate protective clothing as described in Section 8.
6.2 Environmental Precautions:
Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.
6.3 Methods and Material for Containment and Cleaning up:
Collect using an inert non-combustible absorbent material and place in appropriate containers for disposal. Rinse spill area with water. Use non-sparking tools and equipment.
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:
Keep away from high heat and open flames. Use only with adequate ventilation. Avoid breathing mists or vapors. Do not eat, drink, or smoke while using this product. Wear protective clothing and equipment as described in Section 8. Empty containers retain product residues can be hazardous. Follow all SDS precautions when handling empty containers.
7.2 Conditions for Safe Storage, Including Any Incompatibilities:
Do not expose to direct sunlight. Keep containers closed when not in use. Store in a cool, dry, well ventilated area away from incompatible materials. Protect from physical damage.
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
3, 3, 5 trimethyl cyclohexanol methacrylate	None Established
Ethylene Glycol Dimethacrylate (EGDMA)	None Established
Propoxylated bisphenol A urethane dimethacrylate oligomer	None Established
Pentaerythritol tetraacrylate	None Established
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	None Established

Titanium Dioxide*	10 mg/m^3 TWA ACGIH TLV (respirable) 15 mg/m^3 TWA OSHA PEL (total dust) 10 mg/m^3 (inhalable), 4 mg/m^3 (respirable) TWA UK WEL 11 mg/m^3 TWA France OEL (inhalable) 0.3 mg/m^3 TWA (respirable), 2.4 mg/m^3 STEL (respirable) DFG MAK 10 mg/m^3 TWA Belgium OEL
Carbon Black*	3 mg/m^3 TWA ACGIH TLV (inhalable) 3.5 mg/m^3 TWA OSHA PEL 3.5 mg/m^3 TWA; 7 mg/m^3 STEL UK WEL 3.5 mg/m^3 TWA France OEL 3 mg/m^3 TWA Belgium OEL
Butylated Hydroxytoluene	2 mg/m^3 TWA ACGIH TLV (Inhalable fraction and vapor) 10 mg/m^3 TWA DFG MAK (inhalable), 40 mg/m^3 STEL (inhalable) 10 mg/m^3 TWA UK WEL 10 mg/m^3 TWA France OEL 2 mg/m^3 TWA Belgium

* Titanium dioxide and Carbon black are incorporated into a viscous liquid and is not present as a respirable dust. There is no exposure to respirable titanium dioxide or carbon black dust in the normal use of this product.

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.

Individual Protection Measures (PPE)

Specific Eye/face Protection: Wear chemical goggles.

Specific Skin Protection: Wear impervious gloves to prevent skin contact.

Specific Respiratory Protection: None should be needed under normal use. If exposure limits are exceeded an approved respirator or supplied air respirator appropriate should be used. Respirator selection and use should be based on contaminant type, form and concentration. Follow applicable regulations and good Industrial Hygiene practice.

Specific Thermal Hazards: Not applicable

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	Tooth colored viscous liquid	**Explosive limits:**	LEL: Not available UEL: Not available
Color:	Tooth colored	**Physical State:**	Liquid
Odor:	Not determined	**Vapor pressure (mmHg):**	Not determined
Odor threshold:	Not determined	**Relative Vapor Pressure @20ºC:** (Air = 1)	Not determined
pH:	Not applicable	**Density (Relative):**	Not determined
Melting/freezing point:	Not determined	**Solubility:**	Not determined

Initial boiling point and range:	Not determined	**Partition coefficient: n-octanol/water:**	Not available
Flash point:	>200°F (93°C)	**Auto-ignition temperature:**	Not determined
Evaporation rate: (n-BuAc = 1)	Not determined	**Decomposition temperature:**	Not determined
Flammability:	Highly flammable liquid	**Kinematic Viscosity**	Not determined

9.2.1 Properties, Safety Characteristics and Test Results for Physical Hazards: None determined.

9.2.2 Other Safety Characteristics: None determined

10. STABILITY AND REACTIVITY

10.1 Reactivity: May polymerize if exposed to high temperatures or to sunlight.

10.2 Chemical Stability: Stable under normal use conditions.

10.3 Possibility of Hazardous Reactions: None known.

10.4 Conditions to Avoid: Open flames, high temperatures, and sunlight.

10.5 Incompatible materials: Avoid strong oxidizing agents, strong bases and strong acids.

10.6 Hazardous Decomposition Products: Thermal decomposition may release carbon monoxide, carbon dioxide, methacrylates, and irritating smoke.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:
Eyes: Causes serious irritation with redness, pain and tearing.
Skin: Causes skin irritation.
Ingestion: Swallowing may cause gastrointestinal irritation.
Inhalation: Inhalation of mists may cause irritation to mucous membrane and upper respiratory tract.

Chronic Health Effects: None known.

Eye Irritation / Damage: Causes serious irritation with redness, pain and tearing.

Skin Irritation / Corrosivity: Causes skin irritation.

Sensitization: Contains Methyl methacrylate, Urethane acrylate, Pentaerythritol tetraacrylate, and Diphenyl (2,4,6-trimethylbenzoyl) phosphine oxide which may cause an allergic skin reaction.

Carcinogenicity: Based on available data, the classification criteria are not met.
This product may contain a small amount of titanium dioxide or carbon black which are listed by IARC as a suspected carcinogen (Group 2B). Titanium dioxide and carbon black only presents a risk of cancer by inhalation of very fine dust. In this product, the titanium dioxide and carbon black are incorporated into a viscous liquid and are not present as a respirable dust. There is no exposure to respirable dust in the normal use of this product. None of the other components of this product

are listed as carcinogens by OSHA, IARC, ACGIH, the EU CLP, or NTP.

Mutagenicity: Based on available data, the classification criteria are not met.

Aspiration Hazard: Based on available data, the classification criteria are not met.

Acute Toxicity Data:
ATE Product: Oral LD50: >5000 mg/kg
Urethane Methacrylate: Not classified as acutely toxic.
3, 3, 5 trimethyl cyclohexanol methacrylate: Oral rat LD50: >5000 mg/kg; Dermal rat LD50: >2000 mg/kg
Ethylene Glycol Dimethacrylate (EGDMA): Oral rat LD50: >2000 mg/kg; Dermal rat LD50: >2000 mg/kg
Propoxylated bisphenol A urethane dimethacrylate oligomer: Not classified as acutely toxic.
Diphenyl (2,4,6-trimethylbenzoyl) phosphine oxide: Oral rat LD50: >5000 mg/kg; Dermal rat LD50: >2000 mg/kg
Titanium dioxide: Oral rat LD50 - >20000 mg/kg; Dermal hamster LD50 ->10000 mg/kg
Carbon Black: No acutely toxic.
Butylated Hydroxytoluene: Oral rat LD50 - >2000 mg/kg; Dermal rabbit LD50->2000 mg/kg

Reproductive Toxicity Data: Diphenyl (2,4,6-trimethylbenzoyl) phosphine oxide may damage fertility or the unborn child.

Specific Target Organ Toxicity Single Exposure (STOT-SE):
Based on available data, the classification criteria are not met.

Specific Target Organ Toxicity Repeated Exposure (STOT-RE):
Based on available data, the classification criteria are not met.

11.2 Information on Other Hazards

11.2.1 Endocrine Disrupting Properties: None known

12. ECOLOGICAL INFORMATION

12.1 Toxicity: Harmful to aquatic life with long lasting effects.
Urethane Methacrylate: No data available.
3, 3, 5 trimethyl cyclohexanol methacrylate: 96 hr LC50 Danio rerio: 1.89 mg/L; 48hr EC50 Water flea: 14.43 mg/L
Ethylene Glycol Dimethacrylate (EGDMA): 96 hr LC50 Danio rerio: 15.95 mg/L; 48hr EC50 Water flea: 44.9 mg/L
Propoxylated bisphenol A urethane dimethacrylate oligomer: No data available.
Diphenyl (2,4,6-trimethylbenzoyl) phosphine oxide: 96 hr LC50 Cyprinus carpio: 1.4 mg/L;
48hr EC50 Water flea: 3.53 mg/L
Titanium dioxide: Not harmful to the aquatic environment.
Carbon black: Not harmful to the aquatic environment.
Butylated Hydroxytoluene: Daphnia magna EC50: >0.3 mg/l/48hr

12.2 Persistence and Degradability:
Urethane Methacrylate: No data available.
Diphenyl (2,4,6-trimethylbenzoyl) phosphine oxide: Not readily biodegradable.
3, 3, 5 trimethyl cyclohexanol methacrylate: Not readily biodegradable.
Ethylene Glycol Dimethacrylate (EGDMA): Readily biodegradable, but failing 10-day window.

Titanium dioxide: Not applicable to inorganic substances.
12.3 Bio-accumulative Potential: No data available.
12.4 Mobility in Soil: No data available
12.5 Results of PBT and vPvB Assessment: Not required
12.6 Endocrine disrupting Properties: None known.
12.7 Other Adverse Effects: None known

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:
Regulations: Dispose in accordance with local and national regulations
Properties (Physical/Chemical) Affecting Disposal: None known.
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	N/A	Not regulated	N/A	N/A	No
ADR/RID	N/A	Not regulated	N/A	N/A	No
IMDG	N/A	Not regulated	N/A	N/A	No
IATA/ICAO	N/A	Not regulated	N/A	N/A	No

14.6 Special precautions for user: None.

14.7 Transport in Bulk According to IMO Instruments: 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 release reporting under CERCLA. Many other states have more stringent regulations. Report all spills in accordance with local, state, and federal regulations.

Toxic Substances Control Act (TSCA): All of the components of this product are listed on the TSCA inventory.

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: 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): None

State Regulations

California:

WARNING: This product can expose you to chemicals including Styrene, which is known to the State of California to cause cancer, and Toluene, 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

Canada:
This SDS has been prepared according to the criteria of the Canada Hazardous Products Regulation.

Canadian Environmental Protection Act: All of the components in this product are listed on the Domestic Substances list (DSL).

16. OTHER INFORMATION

Full text of Classification abbreviations used in Section 2 and 3:
Aq. Acute 1 - Hazardous to the Aquatic Environment – Acute Hazard Category 3
Aq. Chron. 1 - Hazardous to the Aquatic Environment – Long-Term Hazard Category 1
Aq. Chron. 2 - Hazardous to the Aquatic Environment – Long-Term Hazard Category 2
Aq. Chron. 3 - Hazardous to the Aquatic Environment – Long-Term Hazard Category 3
Carc. 2 – Carcinogen Category 2
Eye Irrit 2 - Eye Irritation Category 2
Repro Tox 1B – Toxic to Reproduction Category 1B.
Skin Irrit. 2 – Skin Irritation Category 2
Skin Sens. 1 Skin Sensitizer Category 1
Skin Sens. 1B Skin Sensitizer Category 1B
STOT SE 3 - Specific Target Organ Toxicity category 3
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation
H336 May cause drowsiness or dizziness.
H351 Suspected of causing cancer.
H360 May damage fertility or the unborn child
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
H411 Toxic to aquatic life with long lasting effects.
H412 Harmful to aquatic life with long lasting effects

Supersedes: 14 October 2021
Date Updated: 24 January 2022
Revision Summary: Revision of CAS number for Diphenyl (2,4,6-trimethylbenzoyl) phosphine oxide and associated changes throughout.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, ECHA REACH Registration Website, Country websites for occupational exposure limits.