



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: 8 January 2019
Document Number: 001027
Date Revised: 10 December 2021
Revision Number: 3

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

1.1 Product Identifier:

Trade Name (as labeled): Lucitone Digital Fit Disc

Part/Item Number: 906110, 906111, 906112, 906113, 906114, 906115, 906116, 906117, 906118, 906119, 906120, 906121, 906122, 906123, 906124, 906125, 906126, 906127, 906128, 906129, 906130, 906131, 906132, 906133, 906134, 906135, 906136, 906137.

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

Recommended Use: Used in the manufacture of dentures and dental appliances

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 Sensitizer Category 1 (H317)	Not Hazardous	Not Hazardous

OSHA Specific Classification: Combustible Dust

2.2 Label Elements:



Signal Word: Warning

Contains: Methyl Methacrylate

Hazard Phrases	Precautionary Phrases
May form combustible dust concentrations in air. H317 May cause an allergic skin reaction.	P261 Avoid breathing dust. P272 Contaminated work clothing must not be allowed out of the workplace. P280 Wear protective gloves. P302+P352 IF ON SKIN: Wash with plenty of water. P333+P313 If skin irritation or rash occurs: Get medical attention. P362+P364 Take off contaminated clothing and wash it before reuse. P501 Dispose of contents and container in accordance with local, regional 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	<1
Titanium Dioxide*	13463-67-7	236-675-5	Carc. 2, H351	<0.5

*Titanium dioxide is inextricably bound within the polymer matrix 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:

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.
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Skin	Remove contaminated clothing and shoes. Flush skin thoroughly with water for several minutes. Get medical attention if irritation or rash occurs. Launder 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. If conscious, wash mouth out with water. Never give anything by mouth to an unconscious or convulsing person. 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. Contact with powder may cause skin sensitization. Individuals with sensitivity to methacrylates may develop an allergic reaction when exposed to this product.	
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, methyl methacrylate, and methyl acrylate.	
5.3 Advice for Fire-Fighters:	
Fire Fighting Procedures/Precautions for Fire Fighters:	Cool fire exposed containers and structures with water. In dusty conditions, 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:	
Avoid contact with disks. For conditions where product dust is released: 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:	
Avoid releases to the environment. Report releases as required by local and national authorities.	
6.3 Methods and Material for Containment and Cleaning up: Pick up and place in a suitable container. For conditions where product dust is released:	
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 Handling:

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, direct sunlight and sources of ignition. Keep away from oxidizing agents and other incompatible materials. Store at temperatures not exceeding 77°F (25°C).

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 EU OEL
Titanium dioxide	15 mg/m ³ TWA OSHA PEL (total dust) 10 mg/m ³ TWA ACGIH TLV 10 mg/m ³ (inhalable) 4 mg/m ³ (respirable dust) TWA UK WEL Belgium: 10 mg/m ³ TWA

Biological Exposure Limits: None 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: None required for normal use. For dusty conditions or during processing wear safety glasses with side-shields or tight fitting goggles or other eye protection consistent with industrial safety practice for the process being performed. In Europe follow EN 166.

Specific Skin Protection: Wear impervious gloves to avoid skin contact. Contact your glove supplier for selection assistance. In Europe follow EN 374.

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 disc shaped solid	Explosive limits:	LEL: Not applicable UEL: Not applicable
Color:	Various colors	Physical State:	Solid
Odor:	Faint methacrylate odor	Vapor pressure (mmHg):	Not applicable
Odor threshold:	Not determined	Relative Vapor Pressure @20°C: (Air = 1)	Not applicable
pH:	Not applicable	Density (Relative):	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: (n-BuAc = 1)	Not applicable	Decomposition temperature:	Not available
Flammability:	Combustible dust	Kinematic Viscosity:	Not applicable

9.2.1 Properties, Safety Characteristics and Test Results for Physical Hazards:

Explosive Properties: High concentrations of dust in the presence of an ignition source could result in a dust explosion.

9.2.2 Other Safety Characteristics: None determined.

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, methyl methacrylate, and methyl acrylate.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: Dust may cause mechanical irritation with redness and tearing.

Skin: May cause irritation, redness, rash and swelling. Prolonged or repeated contact may cause allergic skin reaction (sensitization).

Ingestion: Swallowing large amounts may cause nausea, vomiting and diarrhea.

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

Chronic Health Effects: None expected under normal use.

Eye Irritation/ Damage: Based on available data, the classification criteria are not met.

Skin Irritation / Corrosivity: Based on available data, the classification criteria are not met. Methyl Methacrylate: Moderately to slightly irritating to rabbit skin. This product is not expected to be a skin irritant.

Sensitization: Methyl Methacrylate: Sensitizing in a Mouse local lymph node assay.

Carcinogenicity: Based on available data, the classification criteria are not met. 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. This product contains a small amount of titanium dioxide, which is listed by IARC as a suspected carcinogen (Group 2B). Titanium dioxide only presents a risk of cancer by inhalation of very fine dust. The titanium dioxide is inextricably bound within the polymer matrix of this product. Therefore, there will be no exposure to respirable titanium dioxide during intended use and processing in the form that the product is sold. None of the other components are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU CLP.

Mutagenicity: Based on available data, the classification criteria are not met. Methyl Methacrylate: Negative in AMES test, positive and negative in in-vitro studies. Negative in vivo studies. This product is not expected to cause mutagenic activity.

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

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

Titanium dioxide: Oral rat LD50 > 5000 mg/kg, inhalation rat LC50 > 6.82 mg/L

Reproductive Toxicity Data: Based on available data, the classification criteria are not met. 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/m³. There was no reduction in fertility in a dominant lethal assay in mice

exposed to this compound at concentrations up to 36,900 mg/m³ and no adverse effects on reproductive organs in repeated dose studies conducted to date. This product is not expected to cause adverse reproductive effects.

Specific Target Organ Toxicity Single Exposure (STOT-SE): Based on available data, the classification criteria are not met. 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): Based on available data, the classification criteria are not met. 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: 96 hr LC50 Rainbow trout: >79 mg/L, 48 hr EC50 Daphnia magna: 69 mg/L,
72hr EC50 Pseudokirchnerella subcapitata: >110 mg/L (biomass, growth rate)
Titanium dioxide: 96 hr LC50 Pimephales promelas: > 1000 mg/L

12.2 Persistence and Degradability: Methyl methacrylate 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 required

12.6 Endocrine disrupting Properties: None known.

12.7 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	Not applicable
ADR/RID	None	Not Regulated	None	None	Not applicable
IMDG	None	Not Regulated	None	None	Not applicable
IATA/ICAO	None	Not Regulated	None	None	Not applicable

14.6 Special Precautions for User: Not applicable.

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): Releases above the RQ of 100,000 lbs (based on the RQ for methyl methacrylate of 1,000 lbs present at <1%) 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): 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:

This product contains titanium dioxide which is known to the state of California to cause cancer. However, the titanium dioxide is inextricably bound within the chemical matrix of the product and no exposure can occur.

For more information go to www.P65Warnings.ca.gov.

15.2 Chemical Safety Assessment: None required.

16. OTHER INFORMATION

HMIS Hazard Rating:

Health – 2 Flammability – 2 Physical Hazard – 0

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

Carc. 2 Carcinogen Category 2

Flam. Liq. 2 Flammable Liquid Category 2

Skin Irrit. 2 Skin Irritant Category 2

Skin Sens. 1 Skin Sensitizer Category 1

STOT SE 3 Specific Target Organ Toxicity Single Exposure Category 3

H225 Highly flammable liquid and vapor.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H335 May cause respiratory irritation.

H351 Suspected of causing cancer.

Supersedes: 29 December 2020

Date Updated: 10 December 2021

Revision Summary: Revised for Regulation (EC) 2020/878, Change to Sections: 3, 6, 7, 8, 9, 11, 12, 14, & 15.

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.