

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: 8 August 2016
Document Number: 601
Date Revised: 5 February 2019
Revision Number: 1

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

1.1 Product Identifier:

Trade Name (as labeled): Lucitone® HIPA Denture Base Liquid
Part/Item Number: 682012, 682014, 682015

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
Skin Irritant Category 2 (H315) Skin Sensitization Category 1 (H317) Specific Target Organ Toxicity – Single Exposure Category 3 (H335)	Aquatic Chronic Toxicity Category 3 (H412)	Flammable Liquid Category 2 (H225)

2.2 Label Elements:



Signal Word: Danger

Contains: Methyl Methacrylate

Hazard Phrases	Precautionary Phrases
<p>H225 Highly flammable liquid and vapor. H315 Causes skin irritation. H317 May cause an allergic skin reaction. H335 May cause respiratory irritation. H412 Harmful to aquatic life with long lasting effects.</p>	<p>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 mists, vapors, or spray. P264 Wash thoroughly after handling. P271 Use only outdoors or in a well-ventilated area. P272 Contaminated work clothing must not be allowed out of the workplace. P273 Avoid release to the environment. P280 Wear protective gloves, protective clothing 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. 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. 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 Methacrylate	80-62-6	201-297-1 /	Flam. Liq. 2, H225 Skin Irrit. 2, H315 Skin Sens. 1, H317	70-90

			STOT SE 3, H335	
Methacrylate Ester	Proprietary	Proprietary	Skin Sens. 1A, H317 Aquatic Chronic 2, H411	5-15
Di-functional acrylate	Proprietary	Proprietary	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1B, H317	1-5
Benzotriazole Additive	Proprietary	Proprietary	Skin Sens. 1B, H317 Aquatic Chronic 1, H410	<0.3

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. Get medical attention if irritation occurs and persists.
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	Remove victim to fresh air. Get medical attention if irritation persists.
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:

Direct contact may cause moderate skin irritation. May cause skin sensitization. Individuals with sensitivity to methacrylates may develop an allergic reaction when exposed to this product. Inhalation of mists or vapors may cause moderate respiratory tract irritation.

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 carbon dioxide, foam, water spray or water fog.

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. Heat of fire may cause an exothermic auto polymerization reaction. Closed containers may explode due to pressure build up when exposed to extreme heat. Emits toxic fumes under fire conditions. Decomposition may release carbon monoxide, carbon dioxide, acrylates, 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.
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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 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 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 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. 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
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	50 ppm TWA, 100 ppm STEL DFG MAK
	50 ppm TWA, 100 ppm STEL UK WEL
	50 ppm TWA, 100 ppm STEL EU OEL
Methacrylate Ester	None Established
Di-functional acrylate	None Established
Benzotriazole Additive	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: None should be needed during normal conditions. Splash-proof goggles where contact is possible. Specific Skin Protection: Wear impervious gloves to prevent skin contact. 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:	White liquid	Explosive limits:	LEL: 2.1% UEL: 12.5%
Odor:	Ester-like odor	Vapor pressure (mmHg):	29 mmHg @ 68°F(20°C)
Odor threshold:	Not available	Vapor density: (Air=1)	3.45
pH:	Not available	Relative density:	0.949 g/mL @ 59.9°F (15.5°C)
Melting/freezing point:	-54°F (-48°C)	Solubility(ies):	Slightly soluble. 1.6 g/L @ 68°F(20°C)
Initial boiling point and boiling range:	214°F (101°C)	Partition coefficient: n-octanol/water:	Not available
Flash point:	50°F (10°C) TCC	Auto-ignition temperature:	789.8°F (421°C)
Evaporation rate: (n-BuAc = 1)	>1 (Bac = 1)	Decomposition temperature:	Not available
Flammability (solid, gas):	Not applicable	Viscosity:	Not available
Explosive Properties:	Vapors may be explosive 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. 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, and contamination with polymerization catalysts.

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

10.5 Incompatible materials: Avoid contact with oxidizing agents, reducing agents, acids, and bases.

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

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: Direct contact with liquid and vapors may cause eye irritation with tearing, blurred vision and redness.

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

Ingestion: Small amounts are not anticipated to cause adverse effects. Large quantities may cause gastrointestinal disturbances.

Inhalation: Inhalation of mists or vapors may cause moderate respiratory tract irritation with coughing, mucous production and shortness of breath. High concentration is irritating to the respiratory tract and may cause dizziness, headache and anesthetic effects.

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. Slight to non-irritating to rabbit eyes. Methacrylate Ester: Caused mild skin and eye irritation to rabbit skin and eyes. Benzotriazole Additive: Minimal eye irritation was seen in rabbits.

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

Sensitization: Methyl Methacrylate: Sensitizing in a Mouse local lymphnode assay. Methacrylate Ester: Mouse Local Lymph Node Assay produced an allergic reaction. No skin allergic reaction was observed in Guinea pig maximization test. Benzotriazole Additive: Strong reaction seen in Guinea pig maximization test. No sensitization noted in RIPT (humans) test. Some literatures references sensitization reactions occur in people exposed to cosmetic and plastic formulations containing this chemical.

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 components of this product listed above 0.1% 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.

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

Methacrylate Ester: Oral rat LD50- 4450 mg/kg

Di-functional acrylate: No data available

Benzotriazole Additive: Oral rat LD50- >10000 mg/kg, Inhalation rat LC50- >600 mg/m³, Skin rat LD50- >1000 mg/kg

Aspiration Hazard: Not an aspiration hazard

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/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.

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: 96h LC50 Fathead minnow- 130 mg/L; 48h EC50 Algae- 170 mg/L

Methacrylate Ester: 72 hr ErC50 Desmodesmus subspicatus (green algae)- 2.28 mg/L, 21 days NOEC Daphnia magna- 0.291 mg/L

Benzotriazole Additive: 96 hr LC50 Rainbow trout->0.17 mg/L, 21 days NOEC Daphnia magna- 0.013 mg/L

12.2 Persistence and Degradability: Methyl methacrylate is readily biodegradable - 88% after 28 days. Methacrylate Ester: Readily biodegradable- 74% in 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	14.4 Packing Group	14.5 Environmental Hazards

			Class(s)		
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 1,111 lbs. (based on the RQ for methyl methacrylate of 1,000 lbs. present at 70-90%) 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	70-90%

State Regulations

California:



WARNING: This product can expose you to chemicals including 1,3-Butadiene, which is known to the State of California to cause cancer, and Toluene and 1,3-Butadiene 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

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

Aquatic Chronic 1 Aquatic Chronic Toxicity Category 1

Aquatic Chronic 2 Aquatic Chronic Toxicity Category 2

Eye Irrit. 2 Eye Irritant Category 2

Flam. Liq. 2 Flammable Liquid Category 2

Skin Irrit. 2 Skin Irritant Category 2

Skin Sens. 1 Skin Sensitization Category 1

Skin Sens. 1A Skin Sensitization Category 1A

Skin Sens. 1B Skin Sensitization Category 1B

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.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H410 Very toxic to aquatic life with long lasting effects.

H411 Toxic to aquatic life with long lasting effects

Supersedes: 8 August 2016

Date Updated: 5 February 2019

Revision Summary: Three year update. Revision to California Prop. 65. Changes to Sections 2, 3, 11, 15, & 16.

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