DENTSPLY International

DENTSPLY PROSTHETICS

Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010)

Date Issued: 28 May 2004 Document Number: 151 Date Revised: 5 May 2014 Revision Number: 5

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

1.1 Product Identifier:

Trade Name (as labeled): Lucitone® Liquid
Part/Item Number: 684309, 684315

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

Recommended Use: Fabrication of Dentures

Restrictions on Use: For Professional Use Only

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name: DENTSPLY Prosthetics
Manufacturer/Supplier Address: 570 West College Ave.

York, PA 17401

Manufacturer/Supplier Telephone Number: 717-845-7511 (Product Information)
Email address: Prosthetics MSDS@Dentsply.com

1.4 Emergency Telephone Number:

Emergency Contact Telephone Number: 800-424-9300 Chemtrec

2. HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS Classification:		
Health	Environmental	Physical
Skin Irritant Category 2 (H315)	Not Hazardous	Flammable Liquid Category 2 (H225)
Skin Sensitization Category 1 (H317)		
Specific Target Organ Toxicity-		
Single Exposure Category 3 (H335)		

EU Classification: Highly Flammable (F), Irritant (Xi) R11, R37/38, R43

2.2 Label Elements:

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Signal Word: Danger

Contains: Methyl Methacrylate

Hazard Phrases	Precautionary Phrases
H225 Highly flammable liquid and vapor.	P210 Keep away from heat, sparks, open flames, and hot
H315 Causes skin irritation.	surfaces. No smoking.
H317 May cause an allergic skin reaction.	P233 Keep container tightly closed.
H335 May cause respiratory irritation.	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.
	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.
	P304+P340 IF INHALED: Remove to fresh air and keep at
	rest in a position 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 for extinction.
	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 #	Classification	WT %
Methyl Methacrylate	80-62-6	201-297-1	F, Xi, R11, R37/38, R43	90-99
			Flam. Liq. 2, H225	
			Skin Irrit. 2, H315	
			Skin Sens. 1, H317	
			STOT SE 3, H335	
Ethylene Glycol Dimethacrylate	97-90-5	202-617-2	Xi R37, R43	1-10
			Skin Sens. 1, H317	

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	STOT SE 3, H335	

The exact concentration is being withheld as a trade secret.

Refer to Section 16 for the full text of the GHS and EU Classifications.

4. FIRST AID MEASURES

4.1 Descripti	on of First Aid Measures:
Eye	Flush victim's eyes with large quantities of water, while holding the eyelids apart. Get medical attention if irritation develops or persists.
Skin	Wash skin thoroughly with soap and water. Get medical attention if irritation or rash develops. 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 breathing is difficult or 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:

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.

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

Immediate medical attention should not be required.

Note to Physicians (Treatment, Testing, and Monitoring): Treat symptomatically.

5. FIRE-FIGHTING MEASURES

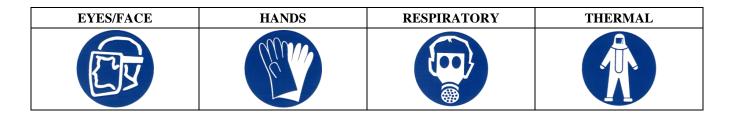
5.1 Extinguishing Media:	Use carbon dioxide, foam, water spray or water fog. Water may be ineffective unless used
5.1 Extinguishing Media.	as a fine spray or fog.

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. 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 and fumes.

5.3 Advice for Fire-Fighters:			
Fire Fighting Procedures:	Fight fire from a safe distance of protected location. Use water to cool fire-exposed		
The Fighting Procedures.	containers.		
Precautions for Fire	Firefighters should wear full emergency equipment and approved positive pressure self-		
Fighters: contained breathing apparatus. Do not enter fire area without proper protection.			
Recommended Protective Equipment for Fire Fighters:			

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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.

Recommen	ded Personal Protective Equi	ipment for Containment and Cle	an-up:
EYES/FACE	HANDS	RESPIRATORY	SKIN

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 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 Handing:

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 can be hazardous. Follow all SDS precautions when handling empty containers.

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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

Occupational Exposure Limits:		
Methyl Methacrylate	United States	50 ppm TWA, 100 ppm STEL ACGIH TLV (Sens) 100 ppm TWA OSHA PEL
	Germany	50 ppm TWA, 100 ppm STEL DFG MAK
	United Kingdom	50 ppm TWA, 100 ppm STEL UK WEL
	European Union	50 ppm TWA, 100 ppm STEL EU OEL
Ethylene Glycol Dimethacrylate	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	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 glasses are recommended where splashing is possible.

Specific Skin Protection: Wear nitrile rubber or other impervious gloves to prevent skin contact. Wear impervious clothing if needed to prevent any contact with this product, such as gloves, apron, boots, or whole body suit.

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

Recommended Personal Protective Equipment EYES/FACE HANDS RESPIRATORY SKIN One of the second protective Equipment and the second protective Equipment Equipment

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9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	Clear liquid	Explosive limits:	LEL: 2.1% UEL: 12.5%
Odor:	Acrylic odor	Vapor pressure (mmHg):	29 mmHg @ 68°F (20°C)
Odor threshold:	0.21 ppm (methyl methacrylate)	Vapor density:	3.45
pH:	Not available	Relative density:	0.94
Melting/freezing point:	-54°F (-48°C)	Solubility(ies):	1.5%
Initial boiling point and boiling range:	Not available	Partition coefficient: n-octanol/water:	Not available
Flash point:	55°F (13°C) TOC	Auto-ignition temperature:	815°F (435°C)
Evaporation rate:	3.1 (Bac=1)	Decomposition temperature:	Not available
Flammability (solid, gas):	Not applicable	Viscosity:	Not available
Explosive Properties:	Vapors are explosive above the LEL	Oxidizing Properties:	None

9.2 Other Information: None available.

10. STABILITY AND REACTIVITY

10.1 Reactivity: May auto polymerize.

10.2 Chemical Stability: Product may become unstable if heated.

10.3 Possibility of Hazardous Reactions: Polymerization can occur. Reaction with oxidizers may cause fire.

10.4 Conditions to Avoid: Conditions leading to polymerization are excessive heat, oxygen-free atmosphere inhibitor depletion (due to excessive aging), direct sunlight, and contamination with polymerization catalysts.

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

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

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

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Potential Health Effects:

Eyes: Liquid and vapor may cause moderate irritation (tears, blurred vision and redness).

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

<u>Ingestion:</u> Ingestion can cause gastrointestinal irritation, a burning sensation of the mouth, throat and gastrointestinal tract and abdominal pain.

<u>Inhalation:</u> May cause 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.

<u>Chronic Health Effects</u>: Prolonged or repeated overexposure may cause skin irritation or sensitization in some individuals, as well as kidney, lung, liver, and heart damage.

<u>Irritation:</u> Methyl Methacrylate: Methyl Methacrylate: Moderately to slightly irritating to rabbit skin. Slightly to non-irritating to rabbit eyes. Ethylene Glycol Dimethacrylate: Not irritating to rabbit eyes

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

<u>Sensitization:</u> Methyl Methacrylate: Sensitizing in a Mouse local lymphnode assay. Ethylene Glycol Dimethacrylate: Found to be an extremely weak sensitizer in the Mouse local lymphnode assay.

<u>Carcinogenicity</u>: 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 are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU CLP.

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

Medical Conditions Aggravated by Exposure:

Individuals with pre-existing skin and respiratory disease may be at increased risk from exposure.

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

Ethylene Glycol Dimethacrylate: Oral rat LD50: 3300 mg/kg; Oral mouse LD50: 2 g/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/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 (STOT):

<u>Single Exposure</u>: 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.

Repeated Exposure: Methyl Methacrylate: Impairment of locomotor activity and learning and behavioral effects on the brain were observed in rats exposed orally to 500 mg/kg bw/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

Ethylene Glycol Dimethacrylate: 96 hr LC50 Zebrafish- 15.95 mg/L; 48 hr EC50 Daphnia magna- 44.9 mg/L

12.2 Persistence and Degradability: Methyl mathacrylate is readily biodegradable - 88% after 28 days. Ethylene Glycol Dimethacrylate: 69% after 28 days- readily biodegradable (but failing 10 day window) in screening tests.

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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:

Regulations: Dispose in accordance with all national and local regulations.

Properties (**Physical/Chemical**) **Affecting Disposal:** This product will polymerize when exposed to sunlight. Empty containers retain product residues and can be hazardous. Follow all SDS precautions when handling empty containers.

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 1,010 lbs (based on the RQ for methyl methacrylate of 1,000 lbs present at 90-99%) 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:

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SARA Section 311/312 (40 CFR 370) Hazard Categories:

Immediate Hazard:	Yes	Pressure Hazard:	No
Delayed Hazard:	No	Reactivity Hazard:	No
Fire Hazard:	Yes		

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	90-99%

State Regulations

California: This product contains the following substances known to the state of California to cause cancer and/or reproductive toxicity:

Components	C.A.S. #	WT %
None		

International Regulations

Canadian Workplace Hazardous Materials Information System (WHMIS): Medical devices are not subject to WHMIS.

Canadian Environmental Protection Act: This product is a medical device and not subject to chemical notification requirements.

This SDS has been prepared according to the criteria of the Controlled Products Regulation (CPR) and the SDS contains all of the information required by the CPR.

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.

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16. OTHER INFORMATION

HMIS Hazard Rating:

Health – 2 Flammability – 3 Physical Hazard – 2

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

F Highly flammable

Xi Irritant

R11 Highly flammable

R37 Irritating to the respiratory system.

R37/38 Irritating to respiratory system and skin.

R43 May cause sensitization by skin contact.

Flam. Liq. 2 Flammable Liquid 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.

H317 May cause an allergic skin reaction.

H335 May cause respiratory irritation.

Supersedes: 9 September 2011

Revision Summary: Converted MSDS to Reach SDS. Updated all sections.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau,

ESIS, Country websites for occupational exposure limits.

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