

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)

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1. PRODUCT IDENTIFICATION

Trade Name (as labeled): Lucitone® FRS™ Flexible Dental Resin

Product Identifier (Part/Item Number): 904853, 904854, 904855, 904856, 904857, 904858

U.N. Number: None

U.N. Dangerous Goods Classification: None

Recommended Use: Used in construction of artificial dentures.

Restrictions on Use: For Professional Use Only

Manufacturer/Supplier Name: Dentsply Prosthetics

Manufacturer/Supplier Address: 570 West College Ave.
York, PA 17405-0872

Manufacturer/Supplier Telephone Number: 717-845-7511 (Product Information)

Emergency Contact Telephone Number: 800-424-9300 Chemtrec

Email address: Prosthetics_MSDS@Dentsply.com

2. HAZARD(s) IDENTIFICATION

EU Classification (1999/45/EC as amended): Not Classified as Hazardous

Labeling in accordance with 1999/45/EC as amended: None required

US Hazard Classification: Not Hazardous





3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Components	C.A.S. #	EINECS #	Substance Classification	WT %
Non-hazardous Resins	Mixture	Mixture	Not applicable	100

4. FIRST-AID MEASURES

Routes of Exposure	First Aid Instructions
Eye	Flush eyes with water, holding the eyelids apart. Get medical attention if irritation persists. If product is hot, flush eyes with water, holding the eyelids apart. Get immediate medical attention.
Skin	Wash skin with soap and water. If product is molten, cool skin with large amounts of water. Do not remove material bonded to the skin. Do not apply salves or ointment. Get immediate medical attention. Launder contaminated clothing before re-use. (Discard contaminated shoes).
Inhalation	Remove victim to fresh air. If breathing is difficult have qualified personnel administer oxygen. If breathing has stopped, administer artificial respiration. Get immediate medical attention.
Ingestion	If small quantities are swallowed, rinse out mouth with water. Do not induce vomiting. Never give anything by mouth to an unconscious or drowsy person. If large amounts are swallowed or if irritation or discomfort occurs, get immediate medical attention.
Most important symptoms of exposure	Contact with molten product may cause thermal burns. Vapors or fumes from molten material may cause eye and respiratory tract irritation.
Note to Physicians (Treatment, Testing, and Monitoring): Treat symptomatically.	


5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media:	Use water fog, carbon dioxide, foam or dry chemical.		
Fire Fighting Procedures:	Cool exposed intact containers with water spray.		
Specific Hazards Arising from the Chemical:	None known		
Precautions for Fire Fighters:	Firefighters should wear full emergency equipment and approved positive pressure self-containing breathing apparatus.		
Recommended Protective Equipment for Fire Fighters:			
EYES/FACE	HANDS	RESPIRATORY	THERMAL
			

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, PPE and Emergency Procedures: Wear appropriate protective equipment as described in Section 8.
Environmental Precautions: None known.
Methods and Materials for Containment and Clean-up: At ambient temperatures, pick up material and place into a container for disposal. If molten, allow material to solidify and cool. Pick up or scrape up and place into a containers for disposal.

Recommended Personal Protective Equipment for Containment and Clean-up:

EYES/FACE	HANDS	RESPIRATORY	THERMAL
			

7. HANDLING AND STORAGE

Precautions for Safe Handling: Avoid contact with molten material. Avoid breathing vapors or fumes. Avoid generating dust. Wear protective clothing and equipment as described in Section 8. Use with adequate ventilation.

Empty containers retain product residues can be hazardous. Follow all MSDS precautions when handling empty containers.

Conditions for Safe Storage: Store in a dry, well ventilated area away from heat, direct sunlight and all sources of ignition.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits:

Non-hazardous Resins	United States	15 mg/m ³ TWA OSHA PEL (Total Dust) , 5 mg/m ³ TWA OSHA PEL (Respirable) (as PNOC)
	Germany	4 mg/m ³ TWA MAK (Inhalable), 1.5 mg/m ³ TWA MAK (Respirable)
	United Kingdom	10 mg/m ³ TWA UK OEL (Inhalable), 4 mg/m ³ TWA UK OEL (Respirable)
	European Union	None Established

Biological Exposure Limits: None established.

Appropriate Engineering Controls: Use with adequate local exhaust ventilation to maintain exposures below the occupational exposure limits.


Individual Protection Measures (PPE)

Specific Eye/face Protection: None needed if handling product at ambient temperatures. Wear safety glasses when handling hot material.

Specific Skin Protection: None needed if handling product at ambient temperatures. Wear insulated gloves when handling hot material. Clothing with long sleeves should be worn when working with molten product.

Specific Respiratory Protection: None should be needed for normal use. If the exposure limits are exceeded a NIOSH approved organic vapor/dust/mist respirator appropriate for the form and concentration of the contaminants should be used. Selection and use of respiratory equipment must be in accordance with OSHA 1910.134 or other applicable regulations and good industrial hygiene practice.

Specific Thermal Hazards: None

Recommended Personal Protective Equipment			
EYES/FACE	HANDS	RESPIRATORY	THERMAL
			
Environmental Exposure Controls: None required for normal use.			
General Hygiene Considerations and Work Practices: Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling.			
Protective Measures During Repair and Maintenance of Contaminated Equipment: Wear appropriate protective clothing and equipment.			

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Pink or colorless granulate resin	Explosive limits:	LEL: Not applicable UEL: Not applicable
Odor:	No odor.	Vapor pressure:	Not applicable
Odor threshold:	Not available	Vapor density:	Not applicable
pH:	Not applicable	Relative density:	1.02
Melting/freezing point:	496°F (258°C)	Solubility:	Negligible
Initial boiling point and range:	Not available	Partition coefficient: n-octanol/water:	Not applicable
Flash point:	Not available	Auto-ignition temperature:	Not available
Evaporation rate:	Not applicable	Decomposition temperature:	Not available
Flammability:	Non flammable	Viscosity:	Not applicable
Explosive Properties:	Not explosive.	Oxidizing Properties:	None

10. STABILITY AND REACTIVITY

Reactivity: None known

Chemical Stability: Stable.
Possibility of Hazardous Reactions: None known.
Conditions to Avoid: Excessive heat (temperatures >662°F/300°C). Keep away heat, sparks or ignition sources.
Incompatible materials: None known.
Hazardous Decomposition Products: Thermal decomposition may release carbon oxides and smoke.

11. TOXICOLOGICAL INFORMATION

Potential Health Effects: <u>Eyes:</u> Dust may cause mechanical irritation. Vapors or fumes may cause eye irritation with redness and tearing. Contact with molten product may cause thermal burns. <u>Skin:</u> Contact with molten product may cause thermal burns. <u>Ingestion:</u> Small amounts are not anticipated to cause adverse effects. Large quantities may cause obstruction of the bowel. <u>Inhalation:</u> Inhalation of vapors or fumes may cause irritation of the eyes, nose and upper respiratory tract. Symptoms include coughing, sneezing and difficulty in breathing.
Chronic Health Effects: None known.
Carcinogenicity: None of the components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU Substances Directive.
Mutagenicity: No data available. Not expected to cause mutagenic activity.
Medical Conditions Aggravated by Exposure: Individuals with pre-existing skin and respiratory disorders may be at increased risk from exposure.
Acute Toxicity Data: Non-hazardous Resins: No data available
Reproductive Toxicity Data: No data available.
Specific Target Organ Toxicity (STOT): <u>Single Exposure:</u> No data available <u>Repeated Exposure:</u> No data available

12. ECOLOGICAL INFORMATION

Toxicity: No toxicity data available. This product is not expected to cause environmental toxicity. ...
Persistence and Degradability: No data available.
Bio-accumulative Potential: No data available
Mobility in Soil: No data available
Other Adverse Effects: No data available

Results of PBT/vPvB Assessment: No data available

13. DISPOSAL CONSIDERATIONS

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

Properties (Physical/Chemical) Affecting Disposal: None currently known.

Waste Treatment Recommendations: None known.

14. TRANSPORT INFORMATION

UN Number:	ADR/RID: None	IMDG: None	IATA: None	DOT: None
UN proper shipping name:	ADR/RID: Not Regulated IMDG: Not Regulated IATA: Not Regulated DOT: Not Regulated			
Transport hazard class(es):	ADR/RID: None	IMDG: None	IATA: None	DOT: None
Packaging group:	ADR/RID: None	IMDG: None	IATA: None	DOT: None
Environmental hazards:	ADR/RID: No	IMDG Marine pollutant: No	IATA: No	DOT: No
Special precautions for user: Not applicable				

15. REGULATORY INFORMATION

U.S. Federal Regulations

US OSHA Hazard Classification: Non-hazardous.

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): This product is not subject to CERCLA reporting requirements. 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 requirements.

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:

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

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372): None

Components	C.A.S. #	WT %
None		

State Regulations

California: This product contains the following substances known to the state of California to cause cancer and/or reproductive toxicity: None.

Components	C.A.S. #	WT %
None		

International Regulations

Canadian Workplace Hazardous Materials Information System (WHMIS): Not a controlled product.

European Inventory of Existing Chemicals (EINECS): This product is a medical device and not subject to chemical notification requirements.

EU REACH: All components requiring registration have been pre-registered.

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.

16. OTHER INFORMATION

HMIS Hazard Rating:

Health –0 Flammability – 0 Reactivity – 0

Full text of Classification abbreviations used in Section 2 and 3: None.

Supersedes: 12 September 2010

Revision Summary: Change in format. Comprehensive review. Changes to 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.