

SAFETY DATA SHEETS

This SDS packet was issued with item:

072759793

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

072759777



MATERIAL SAFETY DATA SHEET

SECTION 1 IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product Name: Luci-Sof® Soft Denture Liner
Product Number: 904552, 904554
MSDS Code Number: 181

Manufacturer: Dentsply Prosthetics
Address: 570 West College Ave.
York, PA 17405-0872
Information Telephone Number: 717-845-7511
Emergency Telephone Number: 800-424-9300 Chemtrec
Email: Prosthetics_MSDS@Dentsply.com

Product Use: Denture Relines

Date of Last Revision: February 22, 2010

SECTION 2 HAZARDS IDENTIFICATION

Emergency Overview: No adverse effects are expected from occupational exposure.

EU Preparation Classification (1999/45/EC): Not classified

SECTION 3 COMPOSITION INFORMATION ON INGREDIENTS

Ingredient	CAS No./EINECS No.	Percent	EC Substance Classification (67/548/EEC)
Dimethyl, methylhydrogen siloxane	68037-59-2 / Not listed	1-5	Not Applicable
Non-hazardous Ingredients	Mixture	95-100	Not Applicable

See Section 16 for further information on EU Classification.

SECTION 4 FIRST AID MEASURES

Eye Contact: Flush eyes with water.

Skin Contact: Wash skin with soap and water.

Ingestion: If swallowed, rinse out mouth with water.

Inhalation: Remove victim to fresh air.

SECTION 5 FIRE FIGHTING PROCEDURES

Extinguishing Media: On large fires, use dry chemical, foam, or water spray. For small fires, use carbon dioxide, dry chemical, or water spray. Water can be used to cool exposed containers.

Firefighting Procedures: Do not enter fire area without proper protection. Fight fire from safe distance or protected location. Firefighters should wear full emergency equipment and approved positive pressure self-contained breathing apparatus.

Unusual Fire/Explosion Hazards: Product may evolve small quantities of hydrogen gas which can accumulate. Adequately ventilate to maintain vapors well below flammability limits.

Known or Anticipated Hazardous Products of Combustion: Carbon monoxide, carbon dioxide, traces of incompletely burned carbon compounds, silicon dioxide, hydrogen, and formaldehyde.

SECTION 6 ACCIDENTAL RELEASE MEASURES

Accidental Release Measures: Wear appropriate protective clothing as described in Section 8. Eliminate all ignition sources. Contain and absorb spills with inert material and transfer to a suitable container for disposal. Do not allow spills to be released into the environment.

Personal Precautions: Avoid contact with skin, eyes or clothing. Avoid breathing vapors.

Environmental Precautions: Do not allow spills to enter sewers or waterways.

SECTION 7 HANDLING AND STORAGE

Handling: Avoid contact with eyes, skin, and clothing. Avoid breathing vapors or mist. Wash thoroughly after handling. Wear protective clothing and equipment as described in Section 8. Use with adequate ventilation. Keep away from heat, sparks and flames.

Storage: Store in a cool, dry, well ventilated area. Product may evolve small quantities of hydrogen gas which can accumulate. Adequately ventilate to maintain vapors well below flammability limits and exposure guidelines. Do not repackage. Do not store in glass containers which may shatter due to pressure build up. Keep container closed and store away from water or moisture.

SECTION 8 EXPOSURE CONTROL/PERSONAL PROTECTION

Occupational Exposure Limits:

Dimethyl, methylhydrogen siloxane	None Established
Non-hazardous Ingredients	None Established

Engineering Controls: Use ventilation that is adequate to keep employee exposure minimal.

Personal Protective Equipment:

Eye Protection: Use safety glasses or goggles.

Skin Protection: None required during the normal use of this product.

Respiratory Protection: None needed during normal conditions.

Other Protective Clothing or Equipment: None needed during normal conditions.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Appearance and Odor: Translucent pink, rubber crepe, very little odor.

Boiling Point: Not available

Melting Point: Not available

Freezing Point: Not available

Specific Gravity: 1.15

Solubility in Water: <0.1

pH: Not available

Vapor Pressure (mmHg): Not available

Vapor Density: Not applicable

Evaporation Rate: >1 (Bac = 1)

Viscosity: Not applicable

% Volatile by Volume: <5%

Flashpoint: Not applicable

Flammable Limits in Air: LEL: N/A

Autoignition Temperature: Not applicable

UEL: N/A

SECTION 10 STABILITY AND REACTIVITY

Stability: Stable.

Conditions to Avoid (stability): None known.

Incompatibility with Other Materials: Avoid contact with oxidizing agents, reducing agents, acids, bases.

Hazardous Decomposition Products: Oxidizing materials can cause a reaction. Water, alcohols, acidic or basic materials, and many metals and metallic compounds, when in contact with the product, can liberate flammable hydrogen gas, which can form explosive mixture in air.

Hazardous Polymerization: Will not occur.

SECTION 11 TOXICOLOGICAL INFORMATION

Potential Health Effects:

Eyes: No adverse effects expected.

Skin: No adverse effects expected.

Inhalation: No adverse effects expected.

Ingestion: No adverse effects expected.

Chronic Health Effects: No adverse effects expected.

Carcinogenicity: None of the components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU directive.

Mutagenicity: No data available.

Medical Conditions Aggravated by Exposure: None known.

Toxicological Data:

Dimethyl, methylhydrogen siloxane: No toxicity data available

Non-hazardous ingredients: No toxicity data available

SECTION 12 ECOLOGICAL INFORMATION

Dimethyl, methylhydrogen siloxane
Non-hazardous ingredients

No data available
No data available

SECTION 13 DISPOSAL CONSIDERATIONS

The product should be disposed of in accordance with Federal, State and local regulations.

SECTION 14 TRANSPORT INFORMATION

DOT Shipping Name: Not Regulated

DOT Hazard Class: N/A

UN Number: N/A

DOT Labels Required (49CFR172.101): N/A

IATA Shipping Name: Not Regulated

IATA Hazard Class: N/A

UN Number: N/A

IATA Hazard Labels Required: N/A

IMDG Shipping Name: Not Regulated

IMDG Class: N/A

UN Number: N/A

IMDG Label: N/A

SECTION 15 REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS:

CERCLA 103 Reportable Quantity: Not regulated under CERCLA. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.

SARA TITLE III:

Hazard Category For Section 311/312: Reactivity.

Section 313 Toxic Chemicals: This product contains the following chemicals subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372):

None

Section 302 Extremely Hazardous Substances (TPQ): None

EPA Toxic Substances Control Act (TSCA) Status: This product is a medical device and not subject to chemical notification requirements.

U.S. STATE REGULATIONS

California Proposition 65: This product contains the following substances known to the state of California to cause cancer and/or reproductive toxicity: None.

INTERNATIONAL REGULATIONS:

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

Canadian WHMIS Classification: Medical devices are not subject to WHMIS.

European Community Labeling: None Required

European Inventory of New and Existing Chemicals Substances (EINECS): 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.

SECTION 16 OTHER INFORMATION

HMIS Hazard Rating:

Health – 0 Fire Hazard – 1 Reactivity – 1

Revision Date: 02/22/2010

Supersedes: 01/18/2007

EU Classes and Risk Phrases for Reference (See Sections 2 and 3):

None

Revision Summary: Added e-mail address Switched Sections 2 and 3. Comprehensive Review.

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: 18 August 2002
Document Number: 181
Date Revised: 13 March 2019
Revision Number: 7

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

1.1 Product Identifier:

Trade Name (as labeled): Luci-Sof® Durable Soft Denture Liner
Part/Item Number: 904552, 904554, 904559

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

Recommended Use: Denture Relines
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
Not Hazardous	Not Hazardous	Not Hazardous

2.2 Label Elements:

None Required

Signal Word: None

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixture:

Hazardous Components	C.A.S. #	EINECS # / REACH Registration #	Classification	WT %
Non-hazardous Ingredients	Proprietary	Proprietary	Not Applicable	100

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	Flush eyes with plenty of water for several minutes, while holding eyelids apart.
Skin	Wash skin with soap and water. Seek medical attention if irritation develops or persists.
Inhalation	Remove victim to fresh air. Get medical attention if irritation develops.
Ingestion	If swallowed, wash mouth out with water.

4.2 Most Important Symptoms and Effects, Both Acute and Delayed:

No adverse effects are expected from occupational exposure.

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

No immediate medical attention is normally required.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media:	On large fires, use dry chemical, foam, or water spray. For small fires, use carbon dioxide, dry chemical, or water spray
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5.2 Special Hazards Arising from the Substance or Mixture:

Adequately ventilate to maintain vapors well below flammability limits. Decomposition may release carbon oxides, traces of incompletely burned carbon compounds, silicon dioxide, hydrogen, and formaldehyde.

5.3 Advice for Fire-Fighters:

Fire Fighting Procedures/Precautions for Fire Fighters:	Do not enter fire area without proper protection. Fight fire from safe distance or protected location. Firefighters should wear full emergency equipment and approved positive pressure self-contained breathing apparatus. Do not enter fire area without proper protection.
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6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Avoid contact with eyes, skin, or clothing. Avoid breathing vapors. Wear appropriate protective clothing as described in Section 8. Avoid breathing vapors or mists. Eliminate all ignition sources

6.2 Environmental Precautions:

Do not allow spills to be released into the environment. Report releases as required by local and national authorities.

6.3 Methods and Material for Containment and Cleaning up:

Contain and absorb spills with inert material and transfer to a suitable container for disposal.

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. Use with adequate ventilation. Wash thoroughly with soap and water after handling. Wash thoroughly with soap and water after handling. Keep away from heat, sparks, and flames.

7.2 Conditions for Safe Storage, Including Any Incompatibilities: Store in a cool, dry, well-ventilated area away. Adequately ventilate to maintain vapors well below flammability limits and exposure guidelines. Do not store in glass containers which may shatter due to pressure build up. Keep container closed and store away from water or moisture.

7.3 Specific End Use (s): For professional use only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

Occupational Exposure Limits:

Non-hazardous Ingredients	None Established
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Biological Exposure Limits: None Established

8.2 Exposure Controls:

Appropriate Engineering Controls: Use adequate general or local exhaust ventilation to minimize exposures.

Individual Protection Measures (PPE):

Specific Eye/face Protection: None should be needed during normal conditions. Wear safety goggles as need to avoid eye contact.

Specific Skin Protection: Wear rubber gloves for prolonged use. Clothing with long sleeves may be needed when working with large quantities.

Specific Respiratory Protection: None should be needed during normal conditions. For operations where the occupational exposure limit is exceeded an approved organic vapor respirator appropriate for the form and concentration of the contaminants should be used. Respirator selection and use should be based on contaminant type, form and concentration. Use 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:	Translucent pink, rubber crepe	Explosive limits:	LEL: Not applicable UEL: Not applicable
Odor:	Very little odor	Vapor pressure (mmHg):	Not available
Odor threshold:	Not determined	Vapor density: (Air = 1)	Not applicable
pH:	Not applicable	Relative density:	1.15
Melting/freezing point:	Not available	Solubility(ies):	<0.1 (solubility in water)
Initial boiling point and boiling range:	Not applicable	Partition coefficient: n-octanol/water:	Not applicable
Flash point:	Not applicable	Auto-ignition temperature:	Not applicable
Evaporation rate: (n-BuAc = 1)	Not applicable	Decomposition temperature:	Not available
Flammability (solid, gas):	Not determined.	Viscosity:	Not applicable
Explosive Properties:	None	Oxidizing Properties:	None

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: Will not occur.

10.2 Chemical Stability: Stable under normal conditions.

10.3 Possibility of Hazardous Reactions: Oxidizing materials can cause a reaction. Water, alcohols, acidic or basic materials, and many metals and metallic compounds, when in contact with the product can liberate flammable hydrogen gas, which can form explosive mixtures in the air.

10.4 Conditions to Avoid: Avoid excessive heat, flames, ignition sources, and direct sunlight.

10.5 Incompatible materials: Oxidizing agents, reducing agents, acids, and bases.

10.6 Hazardous Decomposition Products: Decomposition may release oxides of carbon, traces of incompletely burned carbon compounds, silicon dioxide, hydrogen, and formaldehyde.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Eyes: No adverse effects are expected under normal use.

Skin: No adverse effects are expected under normal use.

<u>Ingestion:</u> No adverse effects are expected under normal use.
<u>Inhalation:</u> No adverse expected under normal use.
<u>Chronic Health Effects:</u> No adverse effects are expected.
<u>Irritation:</u> None of the components have been shown to cause eye or skin irritation.
<u>Corrosivity:</u> This product is not corrosive.
<u>Sensitization:</u> None of the components have been shown to cause sensitization in animals or humans.
<u>Carcinogenicity:</u> None of the components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU CLP.
<u>Mutagenicity:</u> No data is currently available.
<u>Aspiration Hazard:</u> Not an aspiration hazard
<u>Acute Toxicity Data:</u> Non-hazardous Ingredients: No data is currently available
<u>Reproductive Toxicity Data:</u> No data is currently available.
<u>Specific Target Organ Toxicity Single Exposure (STOT-SE):</u> No data is currently available.
<u>Specific Target Organ Toxicity Repeated Exposure (STOT-RE):</u> No data is currently available.

12. ECOLOGICAL INFORMATION

12.1 Toxicity: No data is currently available.
12.2 Persistence and Degradability: No data is currently available.
12.3 Bio-accumulative Potential: No data is currently available.
12.4 Mobility in Soil: No data is currently available.
12.5 Results of PBT and vPvB Assessment: Not applicable
12.6 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	None
ADR/RID	None	Not Regulated	None	None	None
IMDG	None	Not Regulated	None	None	None
IATA/ICAO	None	Not Regulated	None	None	None

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 - product is transported only in packaged form.

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 has a Reportable Quantity (RQ) of 1,000,000 lbs. (based on the RQ for Benzoic Acid of 5,000 lbs listed at <0.5%). Releases above the RQ 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): 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):

Components	C.A.S. #	WT %
Benzoyl Peroxide	94-36-0	<1%

State Regulations

California: This product contains titanium dioxide which is known to the state of California to cause cancer.

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: 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.

15.2 Chemical Safety Assessment: None required.

16. OTHER INFORMATION

HMIS Hazard Rating:

Health –0 Flammability – 1 Physical Hazard– 1

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

None

Supersedes: 9 February 2018

Date Updated: 13 March 2019

Revision Summary: Change to Section 1. Revise Prop 65 statement.

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