



MATERIAL SAFETY DATA SHEET

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

Product Name: PermaSoft® Liquid
Product Number: N811000, N811100, N811500, N812000, N812100, N812500, N814002, N814005
MSDS Code Number: 203

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 Liner

Date of Last Revision: January 12, 2009

SECTION 2 HAZARDS IDENTIFICATION

Emergency Overview: Flammable Liquid and Vapor. May cause eye and skin irritation. Harmful if absorbed through the skin. Inhalation of vapors or mist may cause respiratory irritation and central nervous system effects such as headache, dizziness, drowsiness, nausea and unconsciousness. Prolonged and/or repeated overexposure may cause anemia, kidney and liver damage. May cause adverse reproductive effects based on studies with laboratory animals. Very toxic to aquatic organisms.

EU Preparation Classification (1999/45/EC): Highly Flammable (F), Toxic (T), Dangerous for the Environment (N), R11, R50, R61, R62

SECTION 3 COMPOSITION INFORMATION ON INGREDIENTS

Ingredient	CAS No./EINECS No.	Percent	EC Substance Classification (67/548/EEC)
Dibutyl Phthalate	84-74-2 / 201-557-4	60-90	T, N R50, R61, R62
Ethyl Acetate	141-78-6 / 205-500-4	5-15	F, Xi R11, R36, R66, R67
Ethyl Alcohol	64-17-5 / 200-578-6	1-10	F R11

See Section 16 for further information on EU Classification.

SECTION 4 FIRST AID MEASURES

Eye Contact: Immediately flush eyes with large quantities of water for at least 15 minutes, holding the eyelids apart. Get medical attention if irritation persists.

Skin Contact: Remove contaminated clothing. Immediately wash skin thoroughly with soap and water. If rash, irritation or symptoms develop, get medical attention. Launder clothing before re-use. (Discard contaminated shoes).

Ingestion: Get immediate medical attention. Immediately call poison control center or go to a hospital emergency room. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious or convulsing person.

Inhalation: Immediately 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.

SECTION 5 FIRE FIGHTING PROCEDURES

Extinguishing Media: Use carbon dioxide, alcohol foam or dry chemical. Use water to cool exposed containers and structures and disperse flammable vapors.

Firefighting Procedures: Firefighters should wear full emergency equipment and NIOSH approved positive pressure self-contained breathing apparatus. Do not allow run-off from fire fighting to enter drains or water courses.

Unusual Fire/Explosion Hazards: This product is flammable and forms explosive mixtures with air. Vapors are heavier than air and will travel along surfaces to remote ignition sources and flash back. Closed containers may explode if exposed to extreme heat.

Known or Anticipated Hazardous Products of Combustion: Carbon monoxide and carbon dioxide.

SECTION 6 ACCIDENTAL RELEASE MEASURES

Accidental Release Measures: Evacuate spill area and keep unprotected personnel away. Remove all sources of ignition. Ventilate area with explosion proof equipment. Wear appropriate protective clothing as described in Section 8. Contain and collect using inert absorbent materials and place in appropriate containers for disposal. Use non-sparking tools and equipment. If spill has not ignited, use water spray to disperse the vapors and protect personnel attempting to stop leak. Do not flush to sewer! Report releases as required by local, state and federal authorities.

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

Environmental Precautions: Prevent entry into sewers and waterways. Keep away from drains, surface and groundwater.

SECTION 7 HANDLING AND STORAGE

Handling: Avoid contact with the eyes, skin and clothing. Avoid breathing vapors. Wear protective clothing and equipment as described in Section 8. Use only with adequate ventilation. Wash thoroughly with soap and water after handling. Keep containers closed when not in use. Keep product away from heat, sparks, flames and all other sources of ignition. Do not permit smoking in use or storage areas. Use with non-sparking tools and explosion proof equipment. Electrically bond and ground containers for transfer.

Do not cut, drill, grind or weld on or near containers, even empty containers. Empty containers retain product residues can be hazardous. Follow all MSDS precautions when handling empty containers.

Storage: Store in accordance with regulations for the storage of flammable liquids. Store in a dry, well ventilated area away from heat, direct sunlight and all sources of ignition. Store away from oxidizers and other incompatible materials.

SECTION 8 EXPOSURE CONTROL/PERSONAL PROTECTION

Occupational Exposure Limits:

Ethyl Alcohol	1000 ppm TWA OSHA PEL 1000 ppm TWA ACGIH TLV 500 ppm TWA DFG MAK 1000 ppm TWA UK WEL
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Dibutyl Phthalate	5 mg/m3 TWA OSHA PEL 5 mg/m3 TWA ACGIH TLV 5 mg/m3 TWA UK WEL 10 mg/m3 STEL UK WEL
Ethyl Acetate	400 ppm TWA OSHA PEL 400 ppm TWA ACGIH TLV 400 ppm DFG MAK 200 ppm TWA UK WEL 400 ppm STEL UK WEL

Engineering Controls: Use with adequate local exhaust ventilation to maintain exposures below the occupational exposure limits. Use explosion proof equipment where required.

Personal Protective Equipment:

Eye Protection: Chemical safety glass or chemical splash goggles.

Skin Protection: Wear impervious gloves such as 4H™.

Respiratory Protection: None should be needed for normal use. If the exposure limits are exceeded a NIOSH approved organic vapor 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.

Other Protective Clothing or Equipment: Clothing with long sleeves may be needed when working with large quantities.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Appearance and Odor: Liquid, light in color with a slight odor.

Boiling Point: 171° F (77°C)

Freezing Point: Not available

Solubility in Water: Partially

Vapor Pressure (mmHg): Not available

Evaporation Rate: Not available

% Volatile by Volume: Not available

Flammable Limits in Air:

LEL: 2.0% (as ethyl acetate)

UEL: 19% (as ethyl alcohol)

Melting Point: Not applicable

Specific Gravity: 1.02

pH: Not available

Vapor Density: 9.6 @ 20°C

Viscosity: Not applicable

Flashpoint: 74°F (23°C)

Autoignition Temperature: Not available

SECTION 10 STABILITY AND REACTIVITY

Stability: Stable

Conditions to Avoid: Keep away from heat, sparks and all ignition sources.

Incompatibility with Other Materials: Avoid oxidizing agents and inorganic acids.

Hazardous Decomposition Products: Carbon monoxide and carbon dioxide.

Hazardous Polymerization: Will not occur.

Conditions to Avoid: None known.

SECTION 11 TOXICOLOGICAL INFORMATION

Potential Health Effects:

Eyes: Contact may cause irritation with redness, tearing and stinging.

Skin: May cause skin irritation with redness and itching. Repeated or prolonged contact may cause drying, defatting of the skin and dermatitis. The liquid may be absorbed through the skin causing effects similar to those described under inhalation and ingestion.

Ingestion: Ingestion may cause mucous membrane and gastrointestinal irritation with nausea, vomiting and diarrhea. May cause nervous system depression with symptoms of headache, dizziness, nausea, vomiting, weakness, fatigue, confusion, and unconsciousness.

Inhalation: Inhalation of vapors may cause mucous membrane and respiratory irritation and central nervous system depression with symptoms of headache, dizziness, drowsiness, nausea, vomiting, and unconsciousness. High vapor concentrations may cause burning sensation of the nose and throat and watering of the eyes.

Chronic Health Effects: Repeated skin contact may cause dermatitis. Prolonged overexposure to ethyl acetate may cause anemia with leukocytes and damage to the kidney and liver. Dibutyl phthalate has been shown to cause adverse reproductive effects and birth defects in studies with laboratory animals.

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

Medical Conditions Aggravated by Exposure: Individuals with pre-existing eye, skin, respiratory, liver and kidney disease may be at increased risk from exposure.

Acute Toxicity Data:

Ethyl Alcohol:	Ethanol: Oral Rat LD50 - 7060 mg/kg Inhalation Rat LC50 – 20000 ppm/10hr
Dibutyl Phthalate:	Oral Rat LD50 - 7499 mg/kg Inhalation Mouse LC50 - 25 gm/m ³ /2 hours Skin Rabbit LD50 - >20 mL/kg
Ethyl Acetate:	Oral Rat LD50 - 5620 mg/kg Inhalation Rat LC50 – 200 gm/m ³ Skin Rabbit LD50 – >20 mL/kg

SECTION 12 ECOLOGICAL INFORMATION

Ethyl Alcohol:	96 hr/LC50 fish: >100 mg/l
Dibutyl Phthalate:	96 hr/LC50 fathead minnow: 0.92 mg/l 96 hr/LC50 rainbow trout: 1.6 mg/l 48 hr/EC50 daphnid: 3.0 mg/l
Ethyl Acetate:	96 hr/LC50 Daphnid: 2500 mg/L 48 hr/LC50 Golden orfe: 270 mg/L

Dibutyl phthalate is classified as very toxic to aquatic organisms. Releases to the environment should be avoided.

SECTION 13 DISPOSAL CONSIDERATIONS

Dispose in accordance with national and local regulations.

SECTION 14 TRANSPORT INFORMATION

DOT Shipping Name: Flammable Liquid n.o.s. (Ethyl Acetate, Ethanol)

DOT Hazard Class: 3, PG II

UN Number: UN1993

DOT Labels Required (49CFR172.101): Flammable Liquid

Note: Single packages containing 9 lbs or more are subject to RQ requirements.

IATA Shipping Name: Flammable Liquid n.o.s. (Ethyl Acetate, Ethanol)

IATA Hazard Class: 3, PG II

UN Number: UN1993

IATA Hazard Labels Required: Flammable Liquid

IMDG Shipping Name: Flammable Liquid n.o.s. (Ethyl Acetate, Ethanol)

IMDG Class: 3, PG II

UN Number: UN1993

IMDG Label: Flammable Liquid

SECTION 15 REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS:

CERCLA 103 Reportable Quantity: This product has a Reportable Quantity (RQ) of 9 lbs. based on the RQ for Dibutyl Phthalate of 10 lbs. 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.

SARA TITLE III:

Hazard Category For Section 311/312: Acute Health, Chronic Health, Fire Hazard

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):

Dibutyl Phthalate	84-74-2	60-90%
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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 contain the following substances known to the State of California to cause reproductive toxicity (birth defects): Dibutyl phthalate 60-90% (male, female, developmental)

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: Dibutyl Phthalate



Highly Flammable



Toxic



Dangerous for the Environment

Contains Dibutyl Phthalate: DBP

R50 Very toxic to aquatic organisms.

R60 May impair fertility.

R62 Possible risk of impaired fertility.

S9 Keep container in a well ventilated place.

S16 Keep away from sources of ignition - No Smoking!

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

S45 In case of accident or if you feel unwell, seek medical advice immediately (show label where possible).

S53 Avoid exposure – Obtain special instructions before use.

S60 This material and/or its container must be disposed of as hazardous waste.

Restricted to professional users.

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 – 2* Fire Hazard – 3 Reactivity – 0

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

F Flammable

N Dangerous for the Environment

T Toxic

Xi Irritant

R11 Highly flammable.

R36 Irritating to eyes.

R50 Very toxic to aquatic organisms.

R61 May cause harm to the unborn child.

R62 Possible risk of impaired fertility.

R66 Repeated exposure may cause skin dryness or cracking.

R67 Vapors may cause drowsiness and dizziness.

Revision Date: 01/12/2009

Supersedes: 01/30/2006