

DENTSPLY Tulsa Dental Specialties

Safety Data Sheet

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1. PRODUCT IDENTIFICATION

Trade Name (as labeled): PROLUBE® Root Canal Conditioner

Chemical Name/Classification: PROLUBE Root Canal Conditioner

Product Identifier (Part/Item Number): PROLUBE, PROLUBE100, PLUBEAMP, PROLUBEENDY, PROLUBE3, 673021, 673022, 673023, 673024, 973021

U.N. Number: N/A

U.N. Dangerous Goods Classification: N/A

Recommended Use: Lubricant for hand file and rotary instrumentation

Restrictions on Use: For Dental Use Only

Manufacturer/Supplier Name: DENTSPLY Tulsa Dental Specialties

Manufacturer/Supplier Address: 608 Rolling Hills Drive, Johnson City, TN 37604

Manufacturer/Supplier Telephone Number: (800) 662-1202 (Product Information)

Emergency Contact Telephone Number: 1-800-262-8200

Email address: chemtrec@chemtrec.com

2. HAZARD(s) IDENTIFICATION

Emergency Overview

N/A

Routes of Exposure	Signs and Symptoms	Single, Repeated, or Lifetime Exposure	Severity (Mild, Moderate, Severe)	Acute and Chronic Health Effect(s)	Target Organ(s)
Eye	irritation	single	mild	N/A	N/A
Skin	irritation	single	mild	N/A	N/A
Inhalation	none	none	none	none	N/A
Ingestion	nausea	single	mild	none	N/A
Other					

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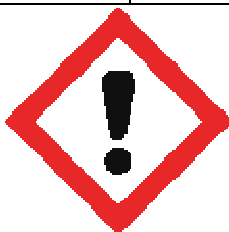
N/A	N/A	N/A	N/A	N/A	N/A
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Hazard/Danger Classification:

Health	Environmental	Physical
N/A	N/A	N/A

Associated Hazards:

Hazard Statements	Precautionary Statements
Causes eye irritation. May be harmful if swallowed. May be harmful if swallowed and enters airways. May be harmful if inhaled	Wear eye protection/face protection. Wash hands thoroughly after handling. Wear protective gloves.



Include as applicable

EU Classification: N/A

EU Risk (R) and Safety (S) Phrases: N/A

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

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Components	C.A.S. # EC#	IUPAC Name	Substance Classification	WT %
Ethylenediaminetetraacetic acid	60-00-4	N/A	N/A	15%
Carbamide peroxide	124-43-6	N/A	N/A	10%

Refer to Section 16 for the full text of the GHS and H phrases and EU Classifications and R Phrases.

4. FIRST-AID MEASURES

Routes of Exposure	First Aid Instructions
Eye	Immediately flush with running water for 15 minutes.
Skin	Wash skin with soapy water and rinse thoroughly
Inhalation	N/A

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Ingestion	Induce vomiting by giving two glasses of water
Most important symptoms of exposure	N/A
Other	N/A
Note to Physicians (Treatment, Testing, and Monitoring)	
N/A	

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media:	Dry powder, CO ₂ , alcohol-resistant foam, water spray.
Fire Fighting Procedures:	Wear self-contained breathing apparatus.
Specific Hazards Arising from the Chemical:	None known. This material is not flammable or combustible.
Precautions for Fire Fighters:	Firefighters should wear full emergency equipment and NIOSH approved positive pressure self-contained breathing apparatus for all fires involving chemicals.

Recommended Protective Equipment for Fire Fighters:

EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, PPE and Emergency Procedures: Pick up mechanically. Must not be disposed together with household garbage.

Environmental Precautions: Do not allow product to reach sewage system or any water course.

Methods and Materials for Containment and Clean-up: Pick up mechanically. Absorb with liquid-binding material (e.g. inert absorbent sand universal binder). Dispose of absorbent material in accordance with local regulations.

Recommended Personal Protective Equipment for Containment and Clean-up:

EYES/FACE	RESPIRATORY
	

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7. HANDLING AND STORAGE

Precautions for Safe Handling: Wash hands thoroughly after handling.

Conditions for Safe Storage: ProLube root canal conditioner can be refrigerated to maintain viscosity. Otherwise, product can be stored at room temperature. Do not expose ProLube root canal conditioner to temperatures exceeding 50°C/122°F

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits: Provide general or local exhaust ventilation.

Biological Exposure Limits: N/A

Appropriate Engineering Controls: N/A

Individual Protection Measures (PPE)

Specific Eye/face Protection: Safety glasses or goggles if eye contact is possible

Specific Skin Protection: protective gloves, apron

Specific Respiratory Protection: provide general or local exhaust

Specific Thermal Hazards: N/A

Recommended Personal Protective Equipment

EYES/FACE	SKIN	RESPIRATORY	THERMAL
		N/A	N/A

Environmental Exposure Controls: Do not allow the product into the following: sewage water, stretches of water or drainage systems.

General Hygiene Considerations and Work Practices: Observe normal care when working with chemicals. Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at the end of work.

Protective Measures During Repair and Maintenance of Contaminated Equipment: Safety glasses, protective gloves, provide general or local exhaust, use of an apron recommended

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9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	White/off white paste	Explosive limits in Air:	Not applicable
Odor:	Slight	Vapor pressure:	(mm Hg.) N.E
Odor threshold:	Not applicable	Vapor density:	(AIR= 1)N.E
pH:	2	Relative density:	1.01 @ 30°C
Melting/freezing point:	40° C / 10° C	Solubility in Water:	Yes
Initial boiling point and range:	Not applicable	Partition coefficient: n-octanol/water:	Not tested
Flash point:	Not applicable	Auto-ignition temperature:	Not applicable
Evaporation rate:	Not applicable	Decomposition temperature:	Not applicable
Flammability Classification :	Not applicable	Viscosity:	Not applicable
Explosive Properties:	Not applicable	Oxidizing Properties:	Not applicable
Exposure to temperatures	Not applicable	Other:	Not applicable

10. STABILITY AND REACTIVITY

Reactivity: Reaction with strong oxidants.
Chemical Stability: light sensitivity, heat sensitivity
Possibility of Hazardous Reactions: Reaction with strong oxidants
Conditions to Avoid: None known
Incompatible materials: None known
Hazardous Decomposition Products: No hazardous decomposition products known.

11. TOXICOLOGICAL INFORMATION

Signs and Symptoms of Overexposure: N/A
Emergency Overview: N/A

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Likely Routes of Exposure	Signs and Symptoms	Single, Repeated, or Lifetime Exposure	Severity (Mild, Moderate, Severe)	Acute and Chronic Health Effect(s)	Target Organ(s)	LD50 Testing Data (as applicable)	LC50 Testing Data (as applicable)
Eye:	Eye contact may cause eye irritation and abrasion.	Single	Mild	Not applicable	Not applicable	Not listed	Not listed
Skin:	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not listed	Not listed
Inhalation:	Direct inhalation may cause irritation to respiratory tract and mucous membranes. Symptoms may include coughing and shortness of breath.	Single	Mild	Not applicable	Not applicable	Not listed	>5.1 mg/l/4h
Ingestion:	Ingestion may cause nausea, choking, vomiting and difficulty swallowing.	Single	Mild	Not applicable	Not applicable	1525 mg/kg	Not listed
Other:	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not listed	Not listed

Medical Conditions Aggravated by Exposure: N/A

Carcinogenicity : N/A

12. ECOLOGICAL INFORMATION

Toxicity: Product is not cytotoxic.

Persistence and Degradability: This product is biodegradable.

Bio-accumulative Potential: Not applicable

Mobility in Soil: Not applicable

Other Adverse Effects: Not applicable

Results of PBT/vPvB Assessment: Not listed

13.DISPOSAL CONSIDERATIONS

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Regulations: Dispose of container and unused contents in accordance with federal, state and local requirements.

Properties (Physical/Chemical) Affecting Disposal: Must not be disposed together with household garbage. Do not allow product to reach sewage system.

Waste Treatment Recommendations: Not applicable

14. TRANSPORT INFORMATION

UN Identification Number: Not applicable

UN Proper Shipping Name: Not applicable

Transport hazard class(es): Not classified as dangerous in transport regulations.

Packing Group: Not applicable

Special precautions for user: Not applicable

15. REGULATORY INFORMATION

U.S. Federal Regulations

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 TSCA requirements.

Clean Water Act (CWA): Not applicable

Clean Air Act (CAA): Not applicable

Superfund Amendments and Reauthorization Act (SARA) Title III Information: None

SARA Section 311/312 (40 CFR 370) Hazard Categories: Not applicable SARA Section 311/312 (40 CFR 370)

Immediate Hazard:	Not applicable	Pressure Hazard:	Not applicable
Delayed Hazard:	Not applicable	Reactivity Hazard:	Not applicable
Fire Hazard:	Not applicable		

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):

Components	C.A.S. #	WT %
Not applicable	Not applicable	Not applicable

State Regulations

California: This product does not contain chemical(s) known to the State of California at this time to cause developmental toxicity, reproductive harm or birth defects.

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Components	C.A.S. #	WT %
Not applicable	Not applicable	Not applicable

International Regulations

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

Canadian Workplace Hazardous Materials Information System (WHMIS): Not applicable

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

16. OTHER INFORMATION

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

Hazard/Danger Classification:

Health - Not applicable

Environmental - Not applicable

Physical - Not applicable

Associated Hazards:

Hazard Statements:

- Causes eye irritation
- May be harmful if swallowed
- May be harmful if swallowed and enters airways
- May be harmful if inhaled

Precautionary Statements:

- Wear eye protection/face protection
- Wash hands thoroughly after handling
- Wear protective gloves

EU Classification - Not applicable

EU Risk (R) and Safety (S) Phrases - Not applicable

Hazardous Components - Hydrogen Peroxide-Urea

C.A.S.#, EC# - 124-43-6

IUPAC Name - Not applicable

Substance Classification - Not applicable

WT% - 2.5-10

Date of SDS Preparation/Revision: 02/18/2014

Data Sources: DENTSPLY Tulsa Dental Specialties